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LOOK-ALIKE DRUGS

HEARING

BEFORE THE

SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL HOUSE OF REPRESENTATIVES

NINETY-SEVENTH CONGRESS

FIRST SESSION

OCTOBER 26, 1981

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CONTENTS

MONDAY, OCTOBER 26, 1981

	Page
Opening statement of Leo C. Zeferetti, chairman, Select Committee on Narcotics Abuse and Control	1
Testimony of Joseph P. Hile, Associate Commissioner for Regulatory Affairs, Food and Drug Administration, accompanied by Edward C. Tocus, Ph. D., Chief, Drug Abuse Staff, Division of Neuropharmacological Drug Products, Bureau of Drugs, Food and Drug Administration, and Jeffrey B. Springer, Deputy Chief Counsel, Food and Drug Division	4
Prepared statement of Joseph P. Hile	6
Testimony of Gene R. Haislip, Director, Office of Compliance and Regulatory Affairs, Drug Enforcement Administration, accompanied by Michael Tobin, Special Agent in Charge, Newark District Office, Drug Enforcement Administration	8
Prepared statement of Gene R. Haislip	11
Testimony of William T. Murphy, Assistant Chief Postal Inspector for Criminal Investigation, U.S. Postal Service, accompanied by David W. Madden, Inspector in Charge, Special Investigations Division, U.S. Postal Service	14
Prepared statement of William T. Murphy	15
Prepared statement of Timothy J. Muris, Director, Bureau of Consumer Protection, Federal Trade Commission	31
Testimony of Harold J. Ruvoldt, Jr., Prosecutor, Hudson County, N.J	32
Prepared statement of Harold J. Ruvoldt, Jr	33
Testimony of Joseph A. Falcone, Prosecutor, Passaic County, N.J., accompanied by First Assistant Prosecutor John P. Goceljak, and Detective Laurence Loughlin	35
Prepared statement of Joseph A. Falcone	37
News Article from West Milford Argus, Sept. 27, 1981	41
Letter to the Editor from D. & E. Pharmaceuticals in Response to News Article which appeared in West Milford Article	44
Testimony of Eric Organ and Todd Weller, D. & E. Pharmaceuticals Co	46
Prepared statement of Eric Organ and Todd Weller	47
Testimony of Lucius Bowser, Chief, Drug Control Program, New Jersey Department of Health	57
Prepared statement of Lucius A. Bowser	58
Testimony of Arthur N. Leibowitz, Pediatrician, Philadelphia, Pa	66
Prepared statement of Arthur N. Leibowitz, M.D.	72
Testimony of James R. Zazzali, Attorney General, State of New Jersey, accompanied by James F. Mulvihill, Assistant Attorney General, Chief, Prosecutors Supervisory Section, and J. Fahy, Deputy Attorney General	75
Prepared statement of Attorney General James R. Zazzali	77
Testimony of Dr. Arthur Zampella, West Milford Youth and Family Advisory Council, West Milford, N.J	80
Prepared statement of Arthur D. Zampella, M.D	82
Testimony of Jeff Hoyak, Editor, The Argus, West Milford, N.J	83
Prepared statement of Jeff Hoyak	84
Testimony of Geraldine Silverman, Millburn Conference of Parents and Teachers, Chairman, Drug Awareness Committee	87

Submissions for the record: Page
Letter to Gene R. Haislip, D.E.A., from Chairman Zeferetti 91
Response to Chairman Zeferetti's letter from Gene R. Haislip 93
Letter to William T. Murphy, U.S. Postal Service, from Chairman Zeferetti 104
Response to Chairman Zeferetti's letter from William T. Murphy 106
Letter to Timothy J. Muris, Federal Trade Commission from Chairman Zeferetti 108
Response to Chairman Zeferetti's letter from Timothy J. Muris 109
Letter to Joseph P. Hile, Food and Drug Administration, from Chairman Zeferetti 112
Response to Chairman Zeferetti's letter from Joseph P. Hile 113
Appendixes:
A—Letter and Comments from Richard S. Gebelein, Attorney General, State of Delaware 125
B—Letter and Comments from Tyrone C. Fahner, Attorney General, State of Illinois 131
C—Position Paper on Look-Alike Drugs presented by New Jersey State Police 136
D—Statement of Walter R. Betyeman, President, New Jersey Narcotic Enforcement Officers Association 138
E—Statement by Warner-Lambert Company 140
F—Statement by Barry M. Diskant, M.D 147
G—Statement of the Proprietary Association 161
H—Letter from Pennwalt Corp. to FDA 181
I—Position Paper presented by Association of Food and Drug Officials 188
J—Article reproduced from the Bulletin of the National Clearinghouse for Poison Control Centers 190
K—News release and letter from the Center for Science in the Public Interest 194
L—Photographs of controlled substances and look-alike substances 198
M—Examples of look-alike promotional materials 200

LOOK-ALIKE DRUGS

MONDAY, OCTOBER 26, 1981

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON NARCOTICS ABUSE AND CONTROL,
Jersey City, N.J.

The select committee met, pursuant to call, at 9 a.m., at Hepburn Hall, Jersey City State College, Jersey City, N.J., Hon. Leo C. Zeferetti (chairman of the select committee) presiding.

Present: Representatives Leo C. Zeferetti, Frank J. Guarini and Benjamin A. Gilman.

Staff present: Patrick L. Carpentier, chief counsel; Roscoe B. Starek III, minority counsel; George R. Gilbert, assistant staff counsel; and Brenda L. Yager, assistant minority counsel.

Mr. ZEFERETTI. The committee will come to order.

Mr. GUARINI. Mr. Chairman, I would like to introduce to you and to Congressman Gilman, and Mr. Carpentier, and to the minority counsel, Ms. Yager, the president of our college, a very outstanding president, whom we are very proud of, Dr. William Maxwell.

Will you come up and welcome our committee?

Dr. MAXWELL. I am very happy to welcome all of you to Jersey City State College.

We are pleased to have you here in New Jersey's only urban State college in the heart of this city. We are very proud of that fact. Many of the students and faculty members of our college will be coming in to hear these proceedings today.

Rather than you, Frank, thanking us for hosting these proceedings, we would rather thank you for the contribution they make to our academic program. We have more than 600 of our students working through our cooperative educational program, governmental, business, industrial organizations, labor organizations, and so we view occasions like this that bring the world of business, government, and labor to our campus as a vital part of our curriculum.

Mr. ZEFERETTI. Thank you very much, Doctor.

Good morning, ladies and gentlemen.

Today, the Select Committee on Narcotics Abuse and Control is holding a public hearing on the subject of "look-alike" drugs. Before proceeding with my remarks, however, I first want to express the sincere appreciation of our entire committee to Dr. Maxwell, president of the Jersey City State College, and to all his staff for inviting us here today to conduct our hearing in this beautiful facility. We thank you very much for all your cooperation and assistance.

Look-alike drugs are pills and tablets that are made to resemble well-known controlled substances, such as amphetamines and

Quaaludes, but contain substances approved by the Food and Drug Administration for over-the-counter drugs. The look-alikes exploit the recreational, nonmedical use of the controlled substances that they are made to duplicate. Manufacturers claim that users of these drugs can get high legally.

The select committee began its investigation into look-alike drugs in the early part of this year. Our inquiry was prompted by mailed flyers and advertisements in magazines that claimed look-alikes to be the "most powerful stimulant available without a prescription."

Proclaimed as "legal stimulants," look-alikes serve no legitimate purpose, but only serve to promote drug abuse. What heightens our concern is the indiscriminate fashion in which look-alikes are being pushed on the American public, especially our young people. To quote one leading distributor of look-alikes, "I want to put these on every breakfast table in America, between the One-A-Day vitamins and the Geritol."

Until recently, the ingredients in look-alikes have been touted as being safe, but there is growing medical evidence to the contrary. At least 11 deaths and numerous injuries have been attributed to look-alike products. The toll may be even higher since look-alikes are often mistaken for the real controlled substances by both police and medical officials.

Moreover, last week the Center for Science in the Public Interest requested the Food and Drug Administration to review one of the major ingredients in look-alikes, phenylpropanolamine [PPA], and ban its use in over-the-counter diet aids.

It is alleged that PPA can cause fatal damage to blood vessels in the brain. The group also petitioned the Federal Trade Commission to halt the advertising of diet products containing PPA that proclaim such products are safe to use.

Today we have called together a broad group of witnesses to aid the committee in developing strategies to bring the look-alike problem under control. We are meeting here in New Jersey at the request of Congressman Frank J. Guarini, a member of the select committee.

Mr. Guarini has expressed concern over the emerging look-alike problem in this State, particularly because New Jersey is situated between major production and distribution centers of look-alikes in New York and Pennsylvania.

Our witnesses include representatives from Federal and State agencies that have been addressing this problem, and concerned community representatives.

I would now like to invite my colleagues to make their opening statements.

Mr. Gilman.

Mr. GILMAN. Thank you, Mr. Chairman. My remarks will be brief. I want to commend you for arranging this hearing at a time when the problem of look-alike drugs has reached alarming proportions for our citizens. I am also delighted to participate with my colleague, the distinguished gentleman from New Jersey, Frank Guarini, in this vitally important hearing, and thank him for inviting us to Jersey City.

The use of look-alike drugs which imitate the appearance of amphetamines, tranquilizers and other substances has become a

new major problem for our Nation. The attempts to cope with the complex difficulty of interdicting narcotics trafficking, in eradicating the illicit production of drugs at their source, in treating and rehabilitating drug dependents and in educating our citizens regarding the dangers of drug abuse have once again been frustrated.

All of this is compounded by the complex problem that so many of our citizens are also becoming polydrug users. In short, the "war" on drug abuse is no longer confined to a "war" against one drug—it has become a war against the illicit trafficking and use of marihuana, heroin, cocaine, hashish, phencyclidine—also known as PCP or angel dust—Quaaludes and other dangerous narcotics, tranquilizers, amphetamines and barbiturates.

Mr. Chairman, in light of this new problem, the manufacture and distribution of look-alike drugs, I am particularly interested in learning from our panelists how our Federal, State, and local officials can more effectively alert our citizens to the dangers of these drugs and what we as legislators can do to assist in that effort.

Thank you, Mr. Chairman.

Mr. ZEFERETTI. Mr. Guarini.

Mr. GUARINI. I want to commend you for the initiative that you have taken in this problem that we have.

Drug abuse knows no party lines and is something that cuts well above political issues. We are all on the same side when it comes to stamping out drug abuse, and as we know here in New Jersey, we are sandwiched between the two major States which are manufacturing these look-alike drugs that have contributed to the health hazards, death, and injuries of many people, and many of them in our high schools, elementary schools, and colleges have succumbed to these types of drugs.

I am very concerned about the fact that there are fly-by-night factories operating these types of profitable businesses, and there are many ripoffs involved in consumer frauds of our people.

I look forward to the testimony to be given, and hopefully we will be able to have some suggestions or recommendations given to us that will lead to a solution of this ever-growing problem.

To my knowledge, there have been very little combined efforts in this area, both on the Federal level, but particularly in the State of New Jersey. We know that there is an increasing problem, and because these drugs are advertised as stimulants, there is very little control; and as a result of the high profits involved, it is a fairly new industry to speak of.

We now have to do something that is going to effectively protect the health of our young people, and indeed all the people of our State. We have here today people from the local prosecutor's level, the attorney general's office of our State, as well as Federal agencies that are involved in the control of trafficking of this kind of material. I look forward to the testimony that is to be given, and hope we will have some good suggestions that will lead to the control of this ever-increasing problem.

[The opening statement of Mr. Guarini follows:]

OPENING STATEMENT OF HON. FRANK J. GUARINI, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. Chairman, members of the Committee, I wish to commend you for taking the initiative to hold hearings on the subject of so-called "look-alike" drugs here in Jersey City, an area located between major look-alike production and distribution centers in New York State and Pennsylvania.

Look-alikes, a phenomenon that most people are not even aware of, have been linked to numerous deaths and injuries to young people all over the country, particularly in the past few months. We are clearly faced with a rapidly growing hazard which must be addressed.

As you know, look-alikes are a combination of substances, primarily caffeine, which are commonly found in cold remedies and diet pills sold over the counter in stores. The danger is often attributed not so much to the actual chemicals, which include, in addition to caffeine: ephedrine and phenylopropanolamine (PPA), but to the excessive amount of those chemicals in each capsule. A single look-alike pill can contain the caffeine content of up to ten cups of coffee, and since users often ingest multiple pills, there is a great potential for tragic side effects such as heart and respiratory failure.

We know that, typically, look-alikes are manufactured to resemble controlled substances by imitating the capsule size, colors and markings of legitimate controlled substances and are generally sold in large quantities. This raises some doubt as to any probable legitimate medical purpose, as they often contain combinations of ingredients that are not recognized as safe nor effective for the relief of cold symptoms, and are boldly advertised as body stimulants.

During a time of reduced spending on all levels of government, we are faced with this growing problem which is infiltrating our schools and undermining existing drug-prevention efforts.

Although a number of states have enacted laws dealing with particular aspects of the look-alike trade, there has been no combined effort in this area.

Today, we hope to not only gain information on the subject of look-alikes, but to particularly explore ways this problem can be contained and eliminated.

Mr. ZEFERETTI. I would like to call up as a panel the following gentlemen, Mr. Joseph Hile, Dr. Edward Tocus, Mr. Jeffrey B. Springer, Mr. Gene Haislip, Mr. Michael Tobin, Mr. William Murphy and Mr. David Madden.

TESTIMONY OF JOSEPH P. HILE, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY EDWARD C. TOCUS, PH. D., CHIEF, DRUG ABUSE STAFF, DIVISION OF NEUROPHARMACOLOGICAL DRUG PRODUCTS, BUREAU OF DRUGS, FOOD AND DRUG ADMINISTRATION, AND JEFFREY B. SPRINGER, DEPUTY CHIEF COUNSEL, FOOD AND DRUG DIVISION

Mr. ZEFERETTI. Good morning. Your statements will be submitted in the record in their entirety. Will you each identify yourselves, so that we have that as part of the record. You may proceed in any manner you choose.

Mr. Hile, would you please start off?

Mr. HILE. Thank you, Mr. Chairman, I will be pleased to do that.

I am Joseph P. Hile, the Associate Commissioner for Regulatory Affairs for the Food and Drug Administration. To my immediate left is Dr. Ed Tocus, the Chief of Drug Abuse Staff in our Bureau of Drugs, and to his left Mr. Jeff Springer, our Deputy Chief Counsel.

I would like to summarize my statement, if I may.

The Food and Drug Administration is a regulatory agency with responsibility for administering the Federal Food, Drug, and Cosmetic Act and related statutes. In the simplest terms, the provisions of the applicable laws are intended to insure that foods,

drugs, and other products under our jurisdiction are safe and effective and honestly and informatively labeled.

The main focus of our laws and the programs designed to implement them is on legitimate products, including legal prescription and nonprescription human drugs.

We employ approximately 1,000 scientifically trained investigators whose job is to inspect food and drug firms to assure that they and their products are in conformance with the various laws and regulations administered by FDA. Information gathered in these inspections is used in all the activities of the agency and may lead to decisions that regulatory action is appropriate. This action may include product seizure, injunction of the firm, and criminal prosecution if warranted.

FDA does not have the authority to routinely file and undertake its own cases. Its recommendations are undertaken on behalf of the Government by the Department of Justice.

Our current role in the controlled substance area became limited to providing the Assistant Secretary for Health, and in turn DEA, with scientific support for scheduling of abuse drugs under the Controlled Substances Act.

For example, the FDA is responsible for monitoring legally marketed drugs, whether or not scheduled, to determine if they have increased in the danger they represent to individuals or if they have become drugs of abuse.

When appropriate, a scientific and medical evaluation and recommendation is prepared for submission to DEA. This recommendation may include initial control, or changes from one schedule to another.

Earlier this year, after a careful review of public health, legal, and resource considerations, the Agency undertook an investigation which has led to seizure actions against the nine major known manufacturers of these drugs.

Seizures were of their inventory of "look-alike" products and the equipment used in the manufacturing process.

This effort required coordination with agencies and officials outside FDA. Seizure complaints were filed by U.S. attorneys in six jurisdictions at the appropriate times, and U.S. marshals conducted the seizures, accompanied by FDA representatives.

The seizures netted approximately 15 million filled capsules and manufactured tablets, many packaged and ready for sale, and more than 20 million empty capsules imprinted with counterfeit markings. Machinery used in the manufacture of the counterfeits, including punches, dies, imprinters, and presses were also seized.

Mr. Chairman, we expect that these recent, well-publicized seizures of drugs and equipment in several different jurisdictions will have a substantial deterrent effect. However, our investigation is still underway and the Agency has yet to conclude whether additional regulatory actions in this area are appropriate.

Because the recent seizure actions are still before the court, legal considerations suggest that we not discuss them in detail here. However, my colleagues and I will be happy to try to answer any other questions that you or other select committee members may have.

[The prepared statement of Mr. Hile follows:]

Prepared Statement of Joseph P. Hile

Mr. Chairman, we welcome the opportunity to participate in this important hearing on the problem of over-the-counter (OTC) "look-alike" drugs.

ROLE OF FDA

The Food and Drug Administration (FDA) is a regulatory Agency with responsibility for administering the Federal Food, Drug, and Cosmetic Act and related statutes. In the simplest terms, the provisions of the applicable laws are intended to ensure that foods, drugs and other products under our jurisdiction are safe and effective and honestly and informatively labeled.

In carrying out our responsibility, we employ a variety of approaches, including premarket clearance of products, inspections of manufacturing establishments, the development and promulgation of standards such as good manufacturing practices regulations, and post-marketing surveillance to determine whether the products themselves or the manner in which they are used are in the best interest of the public health. The main focus of our laws and the programs designed to implement them is on legitimate products, including legal prescription and nonprescription human drugs.

FDA employes approximately 1,000 scientifically trained investigators whose jobs is to inspect food and drug firms to assure that they and their products are in conformance with the various laws and regulations administered by FDA. Information gathered in these inspections is used in all the activities of the Agency and may lead to decisions that regulatory action is appropriate. This action may include product seizure, injunction of the firm and criminal prosecution if warranted.

FDA does not have the authority to routinely file and undertake its own cases. Its recommendations are undertaken on behalf of the Government by the Department of Justice.

RESPONSIBILITY FOR CONTROLLED SUBSTANCES

For a period in our history, FDA exercised authority over the illegal trafficking of certain classes of drugs. This authority was strengthened in 1965, when Congress passed the Drug Abuse Control Amendments to the Federal Food, Drug, and Cosmetic Act which authorized FDA to require legal handlers of habit forming drugs to keep records of their supplies and sales; to seize illegal supplies of this class of controlled drugs; to serve warrants, and to arrest violaters. FDA established at that time a Bureau of Drug Abuse Control in order to implement provisions of the new Act. However, under a 1968 reorganization plan, the Bureau of Drug Abuse Control of FDA and the Bureau of Narcotics of the Treasury Department, were merged to form the Bureau of Narcotics and Dangerous Drugs in the Department of Justice. This agency has not become the Drug Enforcement Administration (DEA) whose authority was expanded and systematized by the Controlled Substances Act of 1970.

With these changes in authority, FDA's role in the controlled substance area became limited to providing the Assistant Secretary for Health and in turn DEA with scientific support for scheduling of abuse drugs under the Controlled Substances Act. For example, the FDA is responsible for monitoring legally marketed drugs, whether or not scheduled, to determine if they have increased in the danger they represent to individuals or if they have become drugs of abuse. When appropriate, a scientific and medical evaluation and recommendation is prepared for submission to DEA. This recommendation may include initial control, or changes from one schedule to another.

With the current roles of FDA and DEA thus outlined, I would now like to turn to the matter of OTC "look-alike" drugs.

BACKGROUND ON "LOOK-ALIKE" DRUGS

This matter arose when a number of small drug manufacturers began to manufacture OTC drug products that mimicked, through size, color, shape and other markings, various prescription drug products that contain substances of abuse, such as amphetamine, barbiturates and tranquilizers, which are regulated under the Controlled Substances Act. The OTC look-alike stimulants contain either a combination of ingredients such as caffeine, phenylpropanolamine and ephedrine or caffeine alone. The OTC look-alike sedatives usually contain one or more antihistamines. Because these OTC look-alikes do not actually contain controlled substances, but only look like they do, they escape regulation under the Controlled Substances Act.

Furthermore, at the manufacturers' level the OTC look-alikes have been labeled correctly as to active ingredient content and the packages are in compliance with

FDA's current OTC drug labeling requirements for use as decongestants, bronchodilators, and over-the-counter stimulants to aid mental alertness. These manufacturers, who are properly registered with FDA, sell to drug distributors, usually on a contract basis, and manufacture the drug products to distributor specifications.

The promotion of these drugs is, of course, different from normal drug industry practice. The distributors advertise in ways that are attractive to the youth of the country that the products are legal stimulants or sedatives. Also the OTC look-alikes are sold at the user level unlabeled and because of their physical appearance, the buyer is led to believe he or she is purchasing a controlled drug.

The manner in which these products are manufactured and distributed presents a special enforcement problem for the Federal Government. Because the drugs in question are OTC products, they escape the enforcement of DEA, the Agency mainly responsible for regulating drug abuse at the "street" level. On the other hand, since FDA's main focus is at the manufacturing level, the street abuse aspects of the problem are outside of the Agency's normal enforcement activities.

PUBLIC HEALTH PROBLEM

To the best of our knowledge, the rapid growth of the OTC look-alike drug traffic is a recent phenomenon and we are unaware of a single health care value or service this fringe industry offers to the consumer. These OTC "look-alike" products have infiltrated secondary schools and college campuses. Children and young adults, though not actually taking controlled drugs, are developing drug abuse habits which may lead them to use of the habit-forming "harder" drugs. Further, the promoters of these drugs state they are "100 percent legal," suggesting a societal blessing to recreational use of drugs and counteracting the effect of the many drug abuse educational programs supported by Government and public organizations for many years. We have received numerous phone calls from parents whose children have received unsolicited literature in the mail from distributors promoting these OTC look-alike drugs. Clearly, OTC look-alikes have become part of the drug abuse problem in this country. So far, there have been 12 reported deaths in which these drugs are associated. In most cases, where the cause of death can be specifically identified, it has been attributed to caffeine intoxication.

The presence of these OTC look-alikes also hinders Federal, State and local law enforcement authorities' efforts to control illegal distribution of prescription controlled drugs. Law enforcement authorities have often spent considerable time, effort and resources in pursuing what appeared to them to be illegally distributed prescription controlled drugs, only to find that the drug products were in fact OTC look-alike products.

Finally, the medical community and poison control centers are hampered by the OTC look-alikes in providing proper medical care and correct antidote treatment in overdose cases, since they are also likely to be mistaken as to the true identity of the drugs in question.

FDA ACTIONS

FDA has encouraged and supported States in their actions to deal with this problem. Currently, 13 States have passed legislation banning distribution of OTC counterfeit drugs and several other States have similar legislation under consideration.

Earlier this year, after a careful review of public health, legal and resource considerations, the Agency undertook an investigation which has led to seizure actions against the nine major known manufacturers of these drugs. Seizures were of their inventory of "look-alike" products and the equipment used in the manufacturing process. This effort required coordination with agencies and officials outside FDA. Seizure complaints were filed by United States attorneys in six jurisdictions at the appropriate times, and United States Marshals conducted the seizures, accompanied by FDA representatives.

The seizures netted approximately 15 million filled capsules and manufactured tablets, many packaged and ready for sale, and more than 20 million empty capsules imprinted with counterfeit markings. Machinery used in the manufacture of the counterfeits, including punches, dies, imprinters and presses were also seized.

CONCLUSION

In conclusion, Mr. Chairman, we expect that these recent, well-publicized seizures of drugs and equipment in several different jursidictions will have a substantial deterrent effect. However, our investigation is still underway and the Agency has yet to conclude whether additional regulatory actions in this area are appropriate.

Because the recent seizure actions are still before the court, legal considerations suggest that we not discuss them in detail here, however, my colleagues and I will be happy to try to answer any other questions that you or other Subcommittee Members may have.

Mr. ZEFERETTI. Thank you, Mr. Hile.

Mr. Haislip.

TESTIMONY OF GENE R. HAISLIP, DIRECTOR, OFFICE OF COMPLIANCE AND REGULATORY AFFAIRS, DRUG ENFORCEMENT ADMINISTRATION, ACCOMPANIED BY MICHAEL TOBIN, SPECIAL AGENT IN CHARGE, NEWARK DISTRICT OFFICE, DRUG ENFORCEMENT ADMINISTRATION

Mr. HAISLIP. My name is Gene Haislip, and I am the Director of the Office of Compliance and Regulatory Affairs for the Drug Enforcement Administration.

Also with me today on my left is Mr. Michael Tobin, the special agent in charge of our Newark office, which is responsible for the enforcement activities of DEA in this area.

I would like to take a few minutes to summarize the more significant items in my statement.

The problem we are looking at here is, I believe the newest, and in a way one of the more disgusting developments in the overall drug abuse problem, because this is unlike the standard criminal activity in which we know that the individuals have complete disregard for society and operate outside the law, the people involved in this particular problem represent themselves to be legitimate businesses and represent themselves to be part of the community making a contribution, and nothing could be further from the case. The problem I am talking about is, of course, the problem of look-alike drugs.

Basically, a number of manufacturers, and a growing number of distributors are intentionally mimicking major drugs of abuse which are controlled under the law and representing in their literature that they are similar or produce the same effect, and that they can be bought cheaply; further, that there is a great deal of profit in their further distribution at the street level, and I think it is important to emphasize that none of the principal legitimate drug manufacturers who supply the Nation's legitimate health needs appear to be involved in this.

As I will develop in a moment, a number of them have taken a very strong stand against this activity and are facilitating the actions to deal with it.

Now, what we have seen in the last 2 or 3 years is a mushrooming of activity of look-alikes. DEA has been monitoring the existence of the problem for perhaps a couple of years, but it was a very spotty and uncertain sort of thing until recently. We have begun to see an explosion of activity because of the high profits to be made.

There are approximately 120 wholesalers operating across the Nation in a number of States, as well as the manufacturers which have thus far been identified, and possibly some additional ones as well, and of course, there is no way to estimate the number of people who are actually dealing in the drugs below the wholesale level.

I think one of the most unfortunate aspects of trafficking in look-alikes is that the effort is clearly designed to mislead and particularly appeal to youth, people who lack sophistication in drugs, and people who may accept this kind of intentionally misleading publicity.

I have a few things that I would like to show you that illustrate this.

I have some examples we have brought from our research testing laboratory and I will identify these if I may pass them to you.

This is a look-alike Quaalude, it has the numbers 714 on it which is precisely the manner in which the legitimate Quaalude tablet that is distributed in the United States is scored.

In one of the photographs you will see a picture of this kind of look-alike produced by another company, and there is a company name on it, they have slightly misspelled it, so it shows the very blatant form in which this kind of counterfeiting is occurring.

Here, we have Dexamyls, these are Dexamyl look-alikes designed to look like the real product, Dexedrine and Preludin, Ionamin, the so-called black beauty which is another major amphetamine subject to abuse in the country for a great period of time.

In addition to these specimens, we have brought to the select committee some of the photographs that show not only the kinds of preparations we are talking about, but some of the irresponsible and misleading type of advertising that accompanies the distribution of these products.

So there can be no misunderstanding as to what these people think they are doing, and that is, getting rich off of the ignorance and to the injury of other people.

It is our view that this should not be countenanced, and we are going to take the actions we can and support other Federal agencies in taking the actions they can.

We hope the States will, too. We see as the principal dangers of this activity is the drugs that are contained in these preparations themselves are approved for use in certain over-the-counter preparations which are fairly common and widely used in society, and generally speaking without any significant degree of harm, when they are consumed in the fashion for which they were intended as antihistamines and nasal decongestants and so forth.

In the quantities that they are frequently consumed when distributed as look-alikes, there is some actual danger from the consumption. We are monitoring this as closely as we can with the statistical systems we have to collect this kind of information, and what we see is that, because they are being sold to abuse, frequently the users will take as many as is necessary in order to produce some kind of effect, and in the case of some of these chemicals, this can be a deadly effect when they take these large doses.

This is particularly true of phenylpropanolamine found in a number of these so-called look-alikes which can produce seizures and actual deaths in a number of known cases.

A further danger, of course, is that those who are ignorant about drugs, which is the kind of people to whom the look-alikes are being peddled, may encounter the real controlled product, and fail to differentiate from the look-alike, and if you take several of

these, it very quickly will kill or injure, so this is an additional danger that derives from this kind of distribution.

Look-alikes are also confusing and confounding medical practitioners who have to deal with drug abuse injuries in the emergency room, because one of the standard techniques for identifying and dealing with these problems is to question the associates or search the body for the kind of medication involved, and frequently, because they are so similar, mistakes may be made in identification, and therefore, there will be an incorrect diagnosis and improper treatment.

A final factor, of course, is the same thing is true in terms of enforcing the controlled substances laws, both at the Federal and State level, and there are a growing number of instances, particularly at the State level, where the police will encounter these drugs, thinking them to be the actual controlled substance.

Finally, most importantly perhaps, the thing we see as the real danger here as much as any other aspect is the fact that the sum total of all this activity in advertising and pandering to this kind of interest is to encourage drug abuse, to try to make it a part of our culture, and establish it as such. And of course, this leads to the vast array of drug abuse problems with drugs which are much more potent and which are more rigidly controlled under the law.

In that sense, we at DEA see that as being somewhat similar to the so-called head shop or drug paraphernalia industry which sprang up some years ago and which still is a major problem in many communities, where the actual goods themselves that are being sold and advertised are not the controlled drugs, but the paraphernalia is used for abusing controlled substances, and therefore, is another way of encouraging the very thing that all of us in society are trying to combat.

We see it as a reprehensible form of activity which has no place in our society and should be completely driven out, not regulated, completely and flatly driven out.

We do not have control under our laws over look-alike drugs. In fact, they are of relatively low potency when used in the prescribed fashion, and probably not suitable for control under our laws.

This has been our judgment for many years and a reexamination of the data would not suggest a change at this time, but nevertheless, because we do feel strongly about it, we are doing what we can. DEA has a six-point planned response to that which is modest. The resources required are modest, but we feel it can have an effect and I will elucidate that in a moment.

The centerpiece for our particular response is to draft a model State law which we will offer to the States for enactment. We based our draft of the law on several pieces of legislation now in existence, so we can come up with a uniform approach to incorporate the best and most effective features that we see.

One of the reasons we are proceeding in this fashion is because we have had exceptionally good luck with the model drug paraphernalia drug law which we drafted. In many States, this law has been enacted, and drug paraphernalia business has been driven completely out.

We see more and more States enacting this law and the very salutory effect is being achieved; we are hopeful and optimistic that it could be achieved in this area, too.

The model act is an important approach and we believe it will receive a great deal of attention and interest from citizens, because this is a problem that strikes them where they live, at their homes, and frequently, perhaps you have had the experience yourselves at concerts and cultural events, people will go to these and come out afterward and find these advertisements plastered all over their windshields.

There is a great deal of citizen knowledge and citizen concern which can be tapped for the kind of concrete action such as the model act we are talking about. To support that, DEA is preparing literature which will explain the act, the problem, provide the basis for legislators, prosecutors, and citizens to take action.

Another important factor, of course, is interagency cooperation at the Federal level, and we have, all of us here at this table, as well as some who are not, have endeavored to cooperate and exchange information and assist each other since early this spring when we conducted our first group meeting, and we have had several, and in addition to that, we have a good deal of active liaison. These frequent contacts have led to very strong direct actions on the part of both the Food and Drug Administration, and the Postal Service who are here with me today and it is a direct result of our getting together, trying to do something about this problem.

A fourth point in our program is to enlist the assistance of legitimate industry. I meet on a quarterly basis with representatives of the drug industry that are involved in controlled substances, the manufacturers, distributors, practitioners, and the pharmacies and I meet with them each separately and we have briefed each group on this problem.

As a result of our briefings a major legitimate firm, which manufactures capsules used in so many of these preparations, called me because they wished to do something about the problem.

We visited their plant and briefed their salespeople in great detail. The result of the briefing was that they have canceled a great many of their orders. This has had a salutory effect with this one company and we are working with others that are involved.

Finally, hearings such as this, an effort to publicize this problem is critical to get the kind of response that we are all seeking.

I hope I have not taken long, however I wanted to discuss some of the important aspects of DEA's program and the concerns we have. I will conclude with that, if I may.

[The prepared statement of Mr. Haislip follows:]

PREPARED STATEMENT OF GENE R. HAISLIP

Chairman Zeferetti and Members of the House Select Committee on Narcotics Abuse and Control: I am pleased to appear before you today and give testimony with regard to yet another novel, but all together contemptible facet of the drug abuse problem which our nation faces. This particular problem involves the production and marketing of drug compounds which when properly marketed and used caused few injuries. In the instant case, however, the whole purpose of a growing number of enterprises is to merchandise these drugs disguised as, and represented as, major drugs of abuse. Before further explaining the details of this traffic in so-called "look-alike" drugs, I should first point out that none of the many responsible

drug companies which supply our legitimate drug needs are known to be involved or in any way have indicated their approval of the imitation drug industry. Nevertheless, "look-alike" businesses are being conducted blatantly and openly as though they were legitimate, and in my opinion they should be permanently deprived of that right.

These look-alikes are tablets and capsules containing noncontrolled over-the-counter drug ingredients, but which are manufactured to closely resemble well-known brand name controlled drugs. When sold on the street, they are removed from containers, devoid of labeling and frequently pass as controlled drugs via slang terms such as "speed," "black beauties," "bam," etc. The monetary incentive for this activity is extremely great. Prices from distributors range from $19 to $150 per 1000 pills which can be sold on the street for $0.50 to $1.50 per pill, a profit of $1000–$1500 for each 1000 capsules sold. Also, there is a clear intent to misrepresent the look-alikes as controlled substances from the manufacturer to the "street" distributor. For example, one look-alike manufacturer is producing a yellow RJ8 capsule (compared to a legitimate RJS Ionamin), another, a pink tablet imprinted BT72 (compared to a legitimate BI62 Preludin) and advertises it as an "effective stimulant" and "highly profitable" for redistribution.

One of the most unfortunate aspects of the look-alike phenomenon is the exploitation of college, high school and even junior high school age students. Large scale advertising campaigns utilizing color brochures, magazine and newspaper ads, highway billboards and flyers have been mounted by look-alike distributors and are aimed primarily at teenagers and young adults. Look-alikes are advertised as body stimulants, energizers or sleep-aids, "a safe, legal way to get high." Distribution of business cards, flyers and other promotional material is common at rock concerts, athletic events, on college campuses, and advertising material is sent through the mail to private residences. A flyer mailed to college campuses had the following wording on the envelope: "TO COLLEGE MAIL HANDLERS, please deliver to dorms that have a high proportion of drug users. We request that this letter be delivered to an individual that needs or uses drugs so he may be given direction and shown the way."

The look-alike phenomenon has shown tremendous growth since 1979 when DEA first became aware of only a handful of distributors. As of September 1981, over 120 wholesale look-alike distributors in almost all sections of the country have been identified. Further, DEA laboratories have received submissions of at least 32 types of black and 17 types of yellow look-alike capsules as of March 1981, compared to 11 and 3 types respectively as of April 1979. In addition, they have also received dozens of other varieties of imitation controlled substances. Escalation of this problem has resulted in a number of states enacting legislation to eliminate the distribution of look-alikes.

The look-alike stimulants mimic the appearance of amphetamine or amphetamine-like products such as Biphetamine, Ionamin, Dexamyl, Dexedrine, Eskatrol, Preludin and Fastin while the most common depressant look-alikes mimic the appearance of Quaalude and Valium. Look-alikes have also been manufactured to imitate the powerful narcotic, Dilaudid. However, they generally contain the following over-the-counter drugs: caffeine, phenylpropanolamine, ephedrine, pseudoephedrine, acetaminophen, salicylamide, doxylamine and chlorpheniramine, either alone or more commonly in combination. Although they are legitimately used as nasal or bronchial decongestants, analgesics or for the relief of cold, allergy or asthma symptoms, these ingredients can also produce either mild stimulant or depressant effects. When taken for their intended medical purpose, in recommended doses and in accordance with FDA labeling, the look-alike ingredients are generally safe and produce only minor side effects. Unfortunately, the look-alike user is lured into believing that these pills will produce effects equal to those of the controlled drugs they mimic. Serious adverse reactions are possible and have occurred when look-alikes are ingested in large quantities in an effort to get the desired effect. Reactions may range from nervousness, insomnia or drowsiness to sharp rises in blood pressure, cerebral hemorrhage and temporary hypertensive episodes. Indeed, emergency rooms reporting to the Drug Abuse Warning Network show an increasing number of individuals seeking emergency medical treatment associated with the use of the ingredients found in look-alikes.

On the other hand, there is the danger to young persons who are accustomed to taking look-alikes and who one day unknowingly ingest equal quantities of actual controlled substances. There is a much greater likelihood of an adverse reaction in these cases, particularly when depressant substances are involved. The medical hazards due to the look-alike phenomenon are further increased by the fact that health care professionals in emergency rooms, poison control centers and drug

abuse clinics are experiencing problems in determining proper treatment for individuals due to the misrepresentation of the look-alikes to the user.

The dangers of the proliferation of look-alikes are not limited to their direct effects on the public health. Time, money and manpower have been wasted by law enforcement personnel in buying or seizing these substances only to find out that no prosecutable crime has been committed. As a result, police in some jurisdictions have ceased buying or seizing pills purported to be controlled stimulants or depressants thus making it easier for drug dealers to peddle the real controlled substance. The novice drug user, after taking look-alikes for a while, may unknowingly think that all controlled substances have the same relatively mild and harmless effect. Perhaps worst of all, the unabated advertising, distribution and use of look-alikes give the impression of societal acceptance of the use of drugs for recreational purposes. This increasing use of psychoactive substances for mood alteration—even in the form of look-alikes—if condoned, can only add to our national drug abuse problem. In this context, look-alikes, much as drug paraphernalia, are part of the overall picture of drug abuse and contribute significantly to its spread among the youth of this country.

The DEA, for the reasons cited above, considers the manufacture, distribution and use of look-alikes to have a substantial and detrimental effect on the general welfare of American society, particularly on our youth. It is a problem which must be dealt with at all levels of government. Efforts against the look-alike problem, however, must take into consideration the facts that the look-alike ingredients have a legitimate medical use, they are found in many of the more common over-the-counter products and, when used as directed, are generally not harmful. DEA has no jurisdiction over look-alike products under the Controlled Substances Act since only noncontrolled substances are involved. However, DEA does have a responsibility to combat drug abuse and considers the look-alike problem to be a facet of drug abuse. The distribution and sale of look-alikes, much as drug paraphernalia, encourages and contributes to the profiteering from drug abuse. For these reasons, DEA has undertaken a six-point program against look-alikes. Briefly, the six points are:

(1) Drafting of a model act for concerned states to adopt.

(2) Preparation of documentation describing the problem, distribution patterns and practices, and other information to be used in support of the model act.

(3) Fostering intergovernmental agency cooperation and providing active support to other agency efforts.

(4) Enlisting the support and/or action of the legitimate pharmaceutical industry.

(5) Publicizing the DEA initiative and encouraging the support of parent and community groups.

(6) Targeting of states heavily involved in look-alike distribution and manufacture to encourage legislative action.

At the heart of this initiative, as was the case with the paraphernalia problem, the Model State Act is targeted to eliminate these undesirable enterprises through the application of regulations and civil and criminal penalties. A number of states have already enacted look-alike legislation. DEA applauds this action and encourages other states to do the same. The DEA Model Act will serve as a guide for States that wish to take legislative action against look-alike manufacturers and distributors. DEA will further attempt to enlist parent, community and industry groups to encourage their support and/or appropriate action. This method of drafting model legislation for states and providing them with the necessary support and expertise has been used with considerable success in attacking and eliminating the sale of drug abuse paraphernalia and should be equally effective against the look-alike phenomenon.

Notwithstanding the role of state and local governments, there is a need for a continuing strong commitment at the Federal level. DEA has provided and will continue to provide active support of other Federal Government efforts. We have met and consulted on a number of occasions with representatives of the U.S. Postal Service, the Food and Drug Administration, the Federal Trade Commission, and the Internal Revenue Service about possible measures to be taken. The action of the DEA on September 30, 1981 against 9 of the look-alike manufacturers will certainly have an impact on the look-alike problem. The efforts of the U.S. Postal Service against a number of distributors is to be similarly applauded. The State of Illinois has also filed complaints against a large number of look-alike distributors. These are appropriate responses and must be continued. It is only through a combined Federal and state effort, in conjunction with industry and community action, that the problems and hazards associated with this latest facet of drug abuse can be minimized or eliminated.

Mr. ZEFERETTI. Thank you, Mr. Haislip.

TESTIMONY OF WILLIAM T. MURPHY, ASSISTANT CHIEF POSTAL INSPECTOR FOR CRIMINAL INVESTIGATION, U.S. POSTAL SERVICE, ACCOMPANIED BY DAVID W. MADDEN, INSPECTOR IN CHARGE, SPECIAL INVESTIGATIONS DIVISION, U.S. POSTAL SERVICE

Mr. MURPHY. Thank you. My name is William Murphy. I am the Assistant Chief Postal Inspector for Criminal Investigations. I am accompanied by David Madden, who is our inspector in charge of the Special Investigations Division.

We have submitted a statement, and with your permission, I will summarize that statement briefly here.

As information, the Postal Inspection Service, as the investigative and law enforcement arm of the Postal Service has the responsibility for the enforcement of those Federal statutes that deal with postal facilities and the mail.

We have two general types of violations, those upon the mail itself, such as post office burglaries, holdups, and thefts from mailboxes, and those in which the mails are used as part of the crime. The most easily recognized of these is mail fraud. We also deal with pornography, the mailing of bombs and this morning's topic, the mailing of narcotics.

I will now move to our concern with the look-alike drugs. About 7 months ago, we began to receive complaints from parents and other concerned citizens dealing with what they felt to be the indiscriminate sale of controlled substances by mail.

There are regulations that provide for the shipment of controlled substances by mail, and there are regulations that provide for the transportation of nonnarcotic prescription drugs by mail, but there are at the same time controls involved in those regulations. Our immediate concern when we received these complaints was, "What was it that was being shipped by mail?"

We undertook a test purchase procedure whereby we obtained the items that were being shipped, and we found that they were over-the-counter type drugs that the general public could buy without a doctor's prescription.

This changed our investigative outlook on the situation and we centered our efforts primarily on the representations that were being made to promote the sale and distribution of these materials.

We found from the evidence that sales targets were essentially younger people—junior high school, high school, and college-age individuals—and that the intent appeared to be for a distributor to sign up a subdistributor who in turn would be given the impression that there was a great profit to be made by the sale of these materials.

In order to obtain this profit, representations had to be made about the capsules or the pills, and essentially they had to mimic the physical appearance of the real thing.

The jargon that was used in the advertisements paralleled that of the actual controlled substances—the "blue and clears," "brown and clears," as Mr. Haislip mentioned, the "714's," "robin eggs," et cetera—names easily recognized by people who dealt with controlled substances, and also by youngsters who might very well resist the temptation for the real thing, but could be tempted by allegedly legal and safe substitutes.

The Postal Inspection Service has taken the position that these articles marketed as they are presently are serious health hazards.

Currently, the Postal Service has filed 39 individual complaints alleging violation of title 39, United States Code, section 3005, which in effect deals with misrepresentations made in soliciting the sale of merchandise by mail.

In our complaints, we alleged that the drug products are misrepresented to be safe, and that they are prepared, labeled and marked in accordance with the food and drug laws.

The complaint also points out that shapes, sizes, colors, and markings resemble, and are easily mistaken for, other brand drugs which contain controlled substances.

At the conclusion of an administrative law judge hearing, section 3005 would permit the Postal Service to return to the sender, mail addressed to the companies found to be in violation.

A more immediate action that is available is an application for a temporary restraining order to withhold the companies' mail until the administrative law judge hearing has been resolved. We have taken such action, filing four TRO requests on September 30, and receiving three temporary restraining orders. We filed for four and received three and the four firms involved have agreed to consent agreements to stop advertising, to remove from all advertising any description of their drug products, and to cease doing business involving the specific products we named in those complaints.

The 39 complaints that we filed relate to 21 distributors in Pennsylvania and to 9 different States. We presently have 31 additional investigations open. I would point out that I believe we are actively pursuing our responsibility in this area, but at the same time, I must indicate that we are limited.

We are limited to mail order transactions, and we must in turn rely on our sister agencies to deal with the nonmail aspects of this.

I appreciate the opportunity to express our views, and we are prepared to answer any questions.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF WILLIAM T. MURPHY

Mr. Chairman, my name is William T. Murphy, and I am the Assistant Chief Postal Inspector for Criminal Investigations. I am accompanied today by Inspector David W. Madden, who is in charge of our Special Investigations Division. I appreciate the opportunity to appear before this committee to discuss the concern of the Postal Service over the sale and distribution by mail of what are commonly referred to as "look-alike" drugs and our efforts to combat this problem.

I would like to begin by telling you a little about the Postal Inspection Service. The Postal Inspection Service is the investigative and audit arm of the U.S. Postal Service. We have investigative jurisdiction and enforcement responsibility over all violations of Federal law relating to the integrity and security of the mails, safety of all postal valuables, property, and personnel. Our law enforcement investigations consist of two major categories: Criminal attacks upon the mails, postal facilities, or postal employees, and those violations which involve the criminal misuse of the postal system itself, such as mail fraud or the mailing of bombs, pornography, or narcotics.

To meet its responsibilities, the Inspection Service has a nationwide complement of approximately 2,000 Postal Inspectors, a uniformed force of 2,500 security police officers, and an appropriate contingent including six forensic crime laboratories. With that introduction, let me move to the purpose of my appearance.

We began our investigation of "look-alike" drugs approximately 7 months ago after receiving complaints from parents and other concerned citizens relating to

what appeared to be the indiscriminate sale and distribution of controlled substances by mail.

Controlled substances can only be legally transmitted in the U.S. mails between persons who are registered with the Drug Enforcement Administration. Prescription medicines containing nonnarcotic drugs may be mailed by a registered practitioner or by a dispenser of drugs to the user. Failure to comply with these mailing requirements would be a violation of title 18, United States Code, section 1716. Our immediate investigative concern, therefore, was to obtain samples of what was being shipped by the U.S. mails.

We obtained samples of the "look-alikes" over a period of several weeks. We determined that the "look-alikes" we had obtained were in fact over-the-counter type products which are available to the general public without a doctor's prescription.

We then centered our investigative efforts on the representations used to promote the sale and distribution of these drugs. It appeared from the advertisements that the intent of the distributor was to provide interested subdistributors with an item that could be resold to the general public at a great profit. To accomplish this, it was necessary to represent these pills and capsules as "real" drugs, "real" amphetamines, "real" quaaludes, and, in some cases, "real" cocaine. Similarly, the physical appearance necessarily mimicked a more potent article. From the evidence, we are convinced that the primary targets for the sale and use of these drugs are junior high, high school, and college-aged individuals. The advertisements used street jargon to describe their products such as "blue and clear," "brown and clear," "robin eggs," "eggs," "714's," and so forth. These names are easily recognized not only by those who deal in the illegal traffic of controlled substances in this country, but also by many youngsters who would not take the "real" thing but could be tempted by an allegedly legal and safe substitute.

The Postal Inspection Service has taken the position that "look-alike" drugs are a potentially serious health hazard and should be considered dangerous when sold and advertised in the manner being used by these companies. Currently, the Postal Service has filed 39 complaints alleging violations of title 39, United States Code, section 3005. Section 3005 permits the Postal Service, upon proper showing before an administrative law judge, to withhold and return to the sender mail addressed to anyone who is engaged in a scheme to obtain money or property by means of false representations. In the complaints filed with the administrative law judge, we allege that the distributors of these "look-alike" drugs make the following false representations: (1) the drug products involved may be safely used by the general population; (2) the drug products involved are prepared, labeled, and marketed in accordance with the Federal food and drug laws. The complaint also points out that the drug products by virtue of their shapes, sizes, colors, and markings resemble and are easily mistaken for certain other brand name drug products which contain controlled substances and that these other drug products are widely recognized by drug abusers who commonly purchase and sell them in the illegal street trade.

A more immediate action available to the Postal Service is a request for a temporary restraining order under title 39, United States Code, section 3007. On September 30, 1981, the Postal Service petitioned the Federal District Court, Middle District of Pennsylvania, for temporary restraining orders against four major mail distributors of "look-alike" drugs. Our investigation has determined that, Clifton Pharmacal Wholesale Inc., Milroy, Pa., Aker's Distributors, Shehan's Distributors, and M. D. Distributing, all of Lewistown, Pa., are either directly or indirectly responsible for a substantial number of the "look-alike" drugs sold in the United States. Three TRO's were issued and subsequently all four firms were issued consent orders to cease doing business involving specific products through the mail and to remove from all advertisements any description of any of their drug products.

The civil administrative complaints we have filed relate to "look-alike" drug distributors located in nine different States including 21 distributors in the Lewistown, Pa., area. We are presently investigating an additional 31 "look-alike" drug distributors located in various parts of the United States. While I believe the Postal Service is diligently pursuing its responsibility in this area, I must point out the Postal Service's administrative authority in these investigations is limited to the "mail order" aspects of these businesses.

We must look to other concerned agencies for dealing with those companies which do not operate primarily through the mails.

Mr. Chairman, I wish to thank you for affording me the opportunity to address your committee to explain the Postal Service's position concerning this serious problem. At this time, Mr. Chairman, I will be more than happy to answer any questions you or members of your committee may have.

Mr. ZEFERETTI. One fact which really concerns me is that we have not made the public aware of what the impact and consequences of the overall look-alike problem. I am happy to hear that you have formed a task force to address the problems and share the intelligence information and communications reports. However, I would like to ask each of you, whether as a result of your task force, you have done anything with regard to criminal prosecution on advertisements and look-alikes that really closely resemble controlled substances.

There is no question about what the manufacturer or distributor is trying to do, and I would like to suggest that maybe we have been a little bit too lenient with these people. Maybe we have not found the right tools to make the kind of impact that could stop some of this.

I share your frustrations, as far as what you can legally do as far as your particular department is concerned. But I also know we have received numerous letters from parent groups, people throughout the country, indicating to us that there must be some tool that we could use to stop this kind of blatant advertisement, because there is no question as to what the intent is. I am asking you collectively, have you evaluated your position to find out whether or not we could prosecute anybody.

We have been too soft. We have all sat back, let these things happen. Now we respond because we get mail, but I would suggest that maybe the response should come from the agencies that have responsibility.

We are here not as adversaries but as partners to find a system, a tool, or something that could lend itself to create that kind of an impact on this situation. I would like to ask you, and have each of you answer in your own way, what can we do collectively to create the impact that is going to give us some kind of public awareness and beyond that, put people on notice that we are not going to tolerate distribution of pills and capsules which kills people, not just injures them. Today it is quite evident that people die as a result of this, and we just want to know from you if there is anything that you feel we can lend toward that effort.

Mr. HILE. We share your outrage over this activity. We agree with you that the agencies, where possible, should look to the possibility of criminal prosecution. Our actions were taken in a step-wise manner. We felt the most appropriate first step was to seize goods that might go into commerce and to seize the equipment that was being used to manufacture those goods. That step has been taken.

Whether or not criminal action will be taken against these firms is still a consideration before the agency.

Mr. ZEFERETTI. Have you made a study in the counterfeit law as to what could be recommended legislatively that could strengthen the present existing laws?

Mr. HILE. We have given preliminary consideration to that, Mr. Chairman, but the Department has not made any recommendations yet regarding new legislation.

Mr. ZEFERETTI. How do you handle the two, the counterfeit drug and the imitation drug?

Mr. HILE. The key difference is the markings, Mr. Chairman. The product must mimic in size, shape, color, and markings, those that are specific to the drug that is being counterfeited. The imitation does not necessarily consider the markings, and that is a more difficult legal consideration for us.

Mr. ZEFERETTI. Would that fall into the fraud statute, if they marked it?

Mr. HILE. It is not an easy matter, Mr. Chairman.

There are two things to consider, and one in all fairness to the legitimate drug trade, is that there are limitations to the number of sizes, shapes and colors that are available. There are literally hundreds of thousands of drug products on the market legitimately and each of those has to have some form and shape, that persons can swallow and all that sort of thing.

In addition, there are arguments that legitimate use of similar shapes and colors among drugs does aid such population groups as the elderly, if they are accustomed to taking drugs of a certain shape, color, and size. For instance, there are several different brand names available and one is considerably less expensive than the other, there are those that argue that the elderly, as an example, should be able to take advantage of that and yet not be distressed over the fact that the drug is appreciably different in appearance.

Mr. ZEFERETTI. Are the ingredients different?

Mr. HILE. The ingredients would be identical in these instances.

Mr. ZEFERETTI. Would they be difficult to obtain?

Mr. HILE. Raw materials can be obtained through normal commerce. The fact is that in the look-alike drugs, there are legitimate uses, long-standing uses for the drugs that are in these over-the-counter look-alike drugs, and a large number of legitimate over-the-counter products contain them and have for any number of years, so that this kind of trafficking does present a more difficult regulatory problem for the involved Federal agency and the State and local agencies, as well.

Mr. ZEFERETTI. But they are copying and mimicking the stronger substances, so they could sell them along those lines.

Mr. Murphy, explain to me, if you will, the procedures you would use when you receive a letter from us indicating we have seen an advertisement in a national magazine that lends itself to a like kind of substance, or if we get a formal complaint from a parent and we send it down to you for an investigation.

How do you handle it? Walk us through the procedure so we know how this situation is handled.

Mr. MURPHY. As I referenced in my statement, one of our initial actions will be to obtain the advertisement and follow through with a purchase to find out exactly what it is that is being offered.

Part of the administrative statute that I mentioned, and a criminal statute as well, deals with the representations that are being made and what is actually furnished.

I do not want to give you the impression that any administrative action ruled out the potential for a criminal action at a later date. Both avenues are viable. However, if there is the possibility of eliminating the problem more quickly through administrative

work, in effect cutting off the benefit or the fruits to the alleged violator, we would probably move quickly in that direction.

We would make that purchase, evaluate what material we received, and if in fact we felt that there was a misrepresentation of the article, we would then file a complaint with the administrative law judge.

Mr. ZEFERETTI. Could you recommend any further Federal authority to give you stronger enforcement power?

Mr. MURPHY. Yes, I might mention that there is a bill, H.R. 3973, at present, which speaks directly to our position; that is, the bill deals with our ability to make those test purchases.

Mr. ZEFERETTI. It is not only a drug investigation?

Mr. MURPHY. No, no. But it would have a direct application in this instance.

Mr. ZEFERETTI. Mr. Haislip, how large would you say this look-alike industry is?

Mr. HAISLIP. Well, first of all, the size has greatly increased in a short period of time. We have a count of 120 distributors, people who have set themselves up in the distributing business and produced advertisements such as the exhibits I have displayed.

There are lower-level distributors who operate informally from their home and we have no count of those. The manufacturers that the Food and Drug Administration have moved against probably does not include all but most, nearly all of those thus far identified.

We are talking here in terms of at least tens of millions of dosage units distributed. I believe we can say that because we can look at the size of the seizure that the Food and Drug Administration made when they moved against the manufacturers. It was some 14 million capsules.

We have some gauge, again, from the capsule manufacturers as to the size of the industry. I would emphasize, Mr. Chairman, if I may, that we certainly share the frustration and outrage about this, very much so, but it is a fairly new, though rapidly-developing, area to which all of us have started to give serious attention as of early this spring. I think that although our authorities are not clear in all cases, that much has been accomplished in a reasonable period of time.

It makes me somewhat optimistic the problem can be dealt with and the main approach to deal with the problem, if I may offer an opinion, sir, more than in individual criminal prosecutions, it is to eliminate this kind of business as a legitimate, or appearing to be legitimate enterprise.

Mr. ZEFERETTI. How does this industry start? How do we market this thing to make it a profit-making operation? It had to start somewhere, it had to develop into something.

Are these very same manufacturers involved in illicit kinds of substances?

Mr. HAISLIP. For the most part this is probably not the case. We have not actually identified any of those enterprises as being also engaged in totally illicit traffic. They are very conscious of the legal differentiations, and they are in fact taking advantage of these vague or gray areas of the law.

This is what they are doing and doing it very intentionally and probably somewhat carefully, I might add, so I don't think that

they are involved in the general illicit traffic that we have to deal with.

If they were, it would probably be easier to deal with in a way.

Mr. ZEFERETTI. You mentioned a drug manufacturing company which sought your advice and was helpful in trying to stop look-alike production. Have we prosecuted any person or company that has not been cooperative?

Mr. HAISLIP. The strongest actions that have been taken to date really have been taken by the two agencies on either side of me. There is a need and a great interest in further actions at the State level.

Approximately 10 States have now active legislation to deal with this problem which is why we are hopeful that the model State act approach will be fruitful. We looked at all of that legislation, and some, we believe, is better than others and we have tried to put together something we think will have the broadest effect.

DEA's chief counsel is in Chicago, or was in Chicago late last week meeting with the State's Attorneys General for the purpose of discussing this activity.

Mr. ZEFERETTI. Mr. Gilman.

Mr. GILMAN. Thank you, Mr. Chairman.

Gentlemen, is there some distinction between the look-alike drugs and the counterfeit drugs with regard to the existing legislation, statutes, the manner in which you treat those?

Mr. HILE. Well, Mr. Gilman, the counterfeit drugs fit from our perspective precisely the definition of counterfeits in the Federal Food, Drug, and Cosmetic Act, which would be the size, shape, color, and the markings.

Differentiation then would be to determine whether or not any of the other drugs which are similar to those that are clearly counterfeit could or should be considered imitations.

The imitation portion of our act goes to the size, shape, and color only, and does not include the more specific requirement of the markings.

Mr. GILMAN. Is there a pretty thin line between the two?

Mr. HILE. Yes, sir, it is, on the streets, I suspect.

Mr. GILMAN. You stated you have some sort of a working relationship. How long have you been getting together? Does that group only include postal, DEA, and FDA?

Mr. HAISLIP. I think FTC has attended.

Mr. GILMAN. How long have you all been involved together as a working group?

Mr. HILE. Yes, it started early this spring; but from a practical standpoint, we have continuing liaison between the two, particularly between DEA and FDA on controlled substances.

Mr. GILMAN. I am asking with regard to the look-alikes and the counterfeits.

Mr. HILE. On the look-alikes specifically, the heavy concentration on this matter started this spring.

Mr. GILMAN. How frequently do you get together?

Mr. HILE. Well, if you include telephone calls and that sort of thing, quite frequently, as often as perhaps one or two times a week.

Mr. GILMAN. How often do you sit down across the table and try to work out a comprehensive plan?

Mr. HAISLIP. We have actually had two large meetings, the first one was in May to do that, but, of course, I have been in touch with the FDA chief counsel's office every 2 or 3 days.

Mr. GILMAN. Has this been your initiative or DEA's, Mr. Haislip?

Mr. HAISLIP. We have taken an active role in the leadership in this area, but we had only leadership to exercise rather than law, but certainly it is true, both these gentlemen have also taken extremely active roles and they have authority to do something which is probably more important.

Mr. GILMAN. In this working group, have you evolved a working plan, some strategy to counteract this infusion of look-alikes in the massive amount of distribution that is going on?

I am talking about the task force.

Mr. HAISLIP. I believe that the actions that have been reported on here by all of us are one of the direct consequences of those meetings.

Mr. GILMAN. Have you evolved some sort of an overall strategy to combat this and recommend some legislative initiatives?

Mr. HAISLIP. We have not.

Mr. GILMAN. How about an overall plan to the administration?

Mr. HAISLIP. I would represent to you is that the measures that we are all taking do add up to a plan. I would not like to be the guarantor that it is going to be the answer. I think that it has a good chance to solve the problem and may solve the problem, but frankly, we need to see if it does and I am not going to represent to you concretely that it will.

I hope it will. There is a good chance that it will. We will need some time to see if it does.

Mr. GILMAN. Is it built basically around the six-point program you suggested in your testimony?

Mr. HAISLIP. No, I would say that the six-point program is DEA's activity and does not reflect the total activity to which you have to add the measures that the other agencies are taking.

Mr. GILMAN. We are dealing with a very sizable amount of distribution and trafficking?

Mr. HAISLIP. Yes.

Mr. GILMAN. How substantial is it? Could you estimate it in dollars for us?

Mr. HAISLIP. I am really unable to do that, to give you something that would be a meaningful estimate.

It is large, but, of course, we deal in such a large volume of illicit traffic, that it certainly is not the same magnitude as some of the problems we have to deal with in the Southeastern United States.

Mr. GILMAN. Are there some statistics available to indicate what you would estimate the extensiveness of this operation is?

Mr. HAISLIP. Some limited statistics are available.

Mr. GILMAN. I would like to ask if you would make those available to the committee and insert them at this point in the record to indicate the amount of sales, the number of firms, dollar estimate of street sales and the sources of the chemicals.

[The information follows:]

Estimates from intelligence sources indicate that during the period January 1980 to June 1981, roughly 30 million dosage units of look-alikes were manufactured each week. Subsequently that number has decreased to 5 million per week. It is likely that sales of look-alikes parallel the amount manufactured.

There are 10 manufacturers and 150 distributors known to DEA as of November 1981.

Assuming a weekly production/sale of 30 million dosage units and an average price of $1.00 per pill ($0.50–$1.50), a $30 million per week estimate of street sales is probable.

The ingredients found in the look-alikes are obtained from legitimate chemical manufacturers and chemical supply houses. For example, there are over 35 companies who can supply caffeine, over 20 who can supply phenylpropanolamine and over 15 who can supply ephedrine in the United States. It is not known which of these firms is supplying the look-alike manufacturer.

Mr. GILMAN. I note in your testimony that some of the chemicals are shipped in from overseas. What are the major sources of that kind of production?

Mr. HAISLIP. The overseas component of this appears to be quite modest at the moment. It is more of a threat or possibility on the aspect of the problem that has to be explored.

For example, we know that capsules are available from overseas manufacturers. At the present time, we have only limited evidence that that source has been tapped. I would say that the international aspects have yet to be fully developed. We are simply aware of the fact that this is an area that could develop.

We have seen extremely severe problems of diversion of controlled drugs overseas, not yet this aspect.

This is just the threat area.

Mr. GILMAN. I am reading from an article where you reported that major amount of the chemical methaqualone are being shipped through free ports in Western Europe such as Hamburg, West Germany. You also go on to mention other areas.

Mr. HAISLIP. If I could clarify that for you, that reference is a different, but extremely important problem of actual smuggling of real methaqualone, not look-alike, but real methaqualone, and it is being smuggled in at approximately 100 to 120 tons a year.

Mr. GILMAN. Is some of that substance being used in any of the look-alikes?

Mr. HAISLIP. No; we do not believe that it is.

If I may correct this, we do not believe that any of that powder is being used by the people involved in this look-alike problem.

The violators who use that methaqualone from Europe do make their own counterfeit look-alikes, but in Colombia, for smuggling into the United States, this is a further complication on the problem, they are counterfeit Quaaludes. It is being done by a different group of people.

Mr. GILMAN. There are foreign producers involved in the look-alike business, is that correct? Are there, or are there not?

Mr. HAISLIP. I will try to explain, if I may.

Mr. GILMAN. By all means.

Mr. HAISLIP. We are really talking about two problems that are distinct and different. The one problem concerns major trafficking in actual controlled drugs, principally methaqualone through Colombia diverted from Europe in enormous quantities.

The look-alikes and the chemicals are a separate problem that involves some American manufacturers, largely the ones——

Mr. GILMAN. Are they using any foreign base?

Mr. HAISLIP. Not yet.

Mr. GILMAN. Are there any foreign producers importing look-alikes into our Nation?

Mr. HAISLIP. Probably not yet.

Mr. GILMAN. We are not involved with any foreign sources when we talk about the look-alike market?

Mr. HAISLIP. Not at the moment. There is the possibility that capsules could be imported for this purpose.

Mr. GILMAN. I am very much concerned because it seems as if we are slapping these people on the wrists without any severe criminal penalties.

Has either the DEA or the Postal Service, or FDA, put any of those people out of business, and do they have the authority to put them out of business?

Mr. MURPHY. We received eight false representation orders against companies.

Mr. GILMAN. What is the penalty for false representation?

Mr. MURPHY. Essentially that particular mail that deals with the product, the mail is cut off to that business, returned to the sender.

Mr. GILMAN. You just stop the mail and tell them you are a bad boy, is that it?

Mr. MURPHY. It goes a little further than that—stopping monetary returns for orders that have been made.

Mr. GILMAN. The seizure only involves that product. There is no other monetary or criminal penalty besides cutting off their postage?

Mr. MURPHY. Under the administrative action that we are talking about, there is no criminal penalty available.

Mr. GILMAN. Mr. Hile, is there any further penalty than just seizure in your agency?

Mr. HILE. Yes, Mr. Gilman, there is. There is the potential for injunction of these firms, to enjoin them from this activity.

Mr. GILMAN. What about the other activities? Any authority for closing up shop?

Mr. HILE. Only through injunctive actions.

Mr. GILMAN. Can you close down the entire production?

Mr. HILE. No, sir, only through the courts as an injunction. To that extent, we can, but we would bear the responsibility to demonstrate that their so-called legitimate business somehow violates other aspects of the act.

Mr. GILMAN. You separate the criminal act from the legitimate act, and you slap them on the wrist for the illegitimate act.

I am not criticizing you, but I want to know what the current status of the law is.

Mr. HILE. The counterfeit provisions provide for the seizure of equipment, as well as the seizure of the product.

Mr. GILMAN. Can you seize all of the equipment in that plant if some of it is being used for illicit purposes such as the manufacturing of look-alike drugs?

Mr. HILE. Yes, sir, any that is being used for the manufacture of counterfeit drugs can be seized and we did seize that equipment. To that extent, some of the firms are out of business.

Mr. GILMAN. How many firms have you put out of business as a result of that type of action?

Mr. HILE. We brought seizure action against nine firms.

Mr. GILMAN. How many have you put out of business?

Mr. HILE. I would suspect seven of them are literally out of business, because their primary business was look-alike drugs. Two of the firms at least had so-called legitimate drug business. They manufactured vitamin and mineral tablets and other over-the-counter-type drugs.

To the extent that their equipment was not involved in the manufacture of look-alikes, it was not seized, and they continue to have the capability to manufacture.

Mr. GILMAN. Are there any penalties imposed against the officers of that plant?

Mr. HILE. That is a potential, yes. We have undertaken an initiative that is a broad initiative.

The first step was to seize goods and equipment. The next is to consider whether or not it is possible for us to impose injunctive action, finally to consider whether or not criminal prosecution is appropriate.

Mr. GILMAN. What is the criminal penalty under those circumstances?

Mr. HILE. It is a misdemeanor, 1 year for every count, and/or $1,000 fine for every count.

Mr. GILMAN. The most stringent penalty is a misdemeanor which normally can be paid off by a fine, is that correct?

Mr. HILE. Under current law, that is correct.

Mr. GILMAN. There is a need for a more stringent penalty?

Mr. HILE. The administrations over the last number of years have introduced legislation which would generally increase our penalties.

Our penalties, even for the so-called legitimate food and drug business, we believe are outdated. They date to 1938, when the act underwent a major overhaul, and I would agree that the penalties need to generally be increased, yes.

Mr. GILMAN. Mr. Haislip, would you agree there is a need for a more stringent penalty in this field?

Mr. HAISLIP. The particular body of law he is addressing is not too familiar to me, but it seems to me, I would agree with that.

Mr. GILMAN. Would the Postal Service also agree?

Mr. MURPHY. If we are talking about mail fraud, it is a $1,000 fine, and a sentence of 5 years. We have had no prosecutions for the drug look-alikes.

Mr. GILMAN. No prosecutions at all?

Mr. MURPHY. No.

Mr. GILMAN. Is there some problem why you have not had any prosecutions? Is the law too difficult to enforce?

Mr. MURPHY. No; but as I mentioned before, we took the administrative action in this instance first.

Mr. GILMAN. That is civil?

Mr. MURPHY. Yes.

Mr. GILMAN. The Postal Service has not embarked on any criminal prosecutions at all in this field?

Mr. MURPHY. Not at this point in the drug look-alikes.

Mr. GILMAN. Has there been any criminal prosecutions DEA has been involved in?

Mr. HAISLIP. No; there have not been. We have no laws that relate to this particular class of drugs which is why we are attempting to approach it through the other avenues.

Mr. GILMAN. Has there been any criminal prosecutions that FDA has been involved with?

Mr. HILE. Not yet.

Mr. GILMAN. According to Mr. Haislip, he said look-alike drugs were becoming one of the major forms of drug abuse in our country, and yet we do not have the proper tools to undertake any kind of enforcement. Is that a correct statement?

Mr. HAISLIP. That is not completely right. With regard to the European part of the problem, that we talked about which involves really controlled drugs, all of our penalties do apply to that.

In the look-alike area, we do not, that is correct.

Mr. GILMAN. Thank you, Mr. Chairman. Apparently there is a need for some stringent legislation that we should pursue.

Mr. ZEFERETTI. Thank you, and to answer a part of your question that you asked earlier, as far as the amount of money that is in this business anyway, there is a report in the Wall Street Journal of September 8 of this year with the headline, "Fake 'Speed' Causes Almost As Much Fear As the Real Thing."

They talk about one distributor who started off selling wholesale out of the back of his truck down in Georgia in 1975, and then into the full drug business with a name as a manufacturer and distributor, and his annual take, after 5 years, was $8 million a year on just these look-alike drugs.

That tells us something.

Mr. Guarini.

Mr. GUARINI. A followup on Mr. Gilman's question, I am curious to know that since the message from Washington is less regulation and less moneys to run our agencies, do you feel that we are going in the wrong direction, that we will have inadequate resources and staff, to prosecute this properly and by our deregulating and decontrolling attitude that we have in Washington today, are these perpetrators more likely to get away with that?

Mr. HAISLIP. A general comment, I think that my colleagues will want to reply. I don't want to comment on the resource question, the budget situation, but to make an important general observation, and that is, within DEA particularly, our resources are, and also will be, so modest, as they must be, because we are talking about 4,000 people, not 400,000, that all Federal action really needs to be strategically targeted.

In other words, it needs to be targeted where a large payoff can be obtained for the smallest investment of resources, and that is what we have to do at DEA, because we only have 2,000 criminal investigators.

If we did not strategically target our efforts, we would really be wasting money and misleading a lot of people. Strategy is really more important than the exact amount of resources, but resources are important, too.

Mr. GUARINI. Do we have adequate resources too, Mr. Haislip?

Mr. HAISLIP. We have enough.

Mr. GUARINI. Do you have enough people, is your agency adequately funded to get the job done?

Mr. HAISLIP. The fact that we have a major significant drug problem is clearly convincing evidence that not enough is being done at any of the levels of the government.

Mr. GUARINI. Does the look-alike problem have a major priority within your Department, considering the fact you have an increasing narcotic and drug abuse problem in our country, or was this on a lower priority?

Mr. HAISLIP. This poses major problems for us, of course.

What we try to do to respond to that is to design the most strategic approach that we can to it, and I wouldn't say to you that it has a low priority, because it does not.

We are really concerned and somewhat infuriated by the existence of this kind of problem.

Mr. GUARINI. It does not enjoy your highest priority?

Mr. HAISLIP. We are giving it everything that we can, all the attention that we have. We are giving it the maximum attention that we can, given the various problems and obligations we have to meet.

Mr. GUARINI. Mr. Hile, would you comment on those responses?

Mr. HILE. I can only echo the remarks that you always can use more resources, if you are to undertake activity against all of the matters that come before you, but from our standpoint in the Food and Drug Administration, this matter is one of the high-priority matters with which we have to deal, and we at least as of the moment have the resources necessary to deal with the information that is before us.

Mr. GUARINI. In your view, has the availability of amphetamines which has been loosened by the FDA over past years for diet prescriptions exacerbated the problem we have today with this look-alike drug situation?

Mr. HILE. I will ask Dr. Tocus to give you some insight into that. We have tightened the use of amphetamines.

Mr. GUARINI. Do you feel, Doctor, that there should be more tightening and in that way approach the solution?

Dr. TOCUS. With specific reference to the amphetamines, we have currently the most stringent controls over amphetamines that we are capable of placing. Those are schedule 2 drugs. We determine the least amount through the quota provision to allow manufacture, just sufficient to supply the legitimate use in our estimation.

Mr. GUARINI. This diet pill business is growing all the time, and your Department has complete control over it. This is one of the most commonly abused over-the-counter drugs, that which is the subject matter of our meeting here today.

Dr. TOCUS. Yes, sir.

Mr. GUARINI. Suppose we do solve the problem of counterfeiting, and people do properly market with their own tablet, the caffeine or the PPA or whatever the substance is. How then would we approach the solution to our problem, since we are talking about look-alike drugs. Suppose they say, look, now that we have developed the market, and we have knocked out the counterfeiting, we don't have to do it in capsules anymore. We will make our own

tablets and market what the FDA allows as a controlled substance today, or as a noncontrolled substance.

Is there any thought of extending these drugs, that are now so easily available to the public, to controlled drugs?

Mr. HILE. We have a continuing responsibility to monitor the marketplace, and as information comes to us that begins to build and be sufficient to support a recommendation on any drug, that it has become a drug of abuse, we would gather that information and make such a recommendation to the DEA.

Now, currently, the drugs that are subject to the OTC look-alike investigation are drugs that have been legitimately used for many, many years in OTC products, available on the marketplace.

The 1962 Drug Amendments required drugs on the marketplace prior to that time, and that includes almost all of these drugs and the combinations, be reviewed for safety and efficacy, and as a result the Agency undertook an extensive review of all over-the-counter drugs on the marketplace.

Mr. GUARINI. In spite of that, we still have violations of PPA and caffeine, and the other things that are permitted in excessive quantities, with no prescription, no control.

We can solve the problems of consumer fraud statutes and the capsule problems. There are three manufacturers that would cooperate completely. There is no illegal marketing or improper statement. We can solve all those things but yet these substances would still be permissible by these fly-by-night manufacturers, since they can make them down in the basement, making millions of dollars peddling to the youth of our country, and continue to be a health hazard.

What is the FDA trying to do about that?

Mr. HILE. Your concerns are legitimate, and to build on my earlier remarks, these drug products have all been reviewed by expert panels composed of physicians and other scientific experts in the field to determine whether or not in legitimate use they should continue to be made available to the American public.

The drug of the greatest concern on the part of the committee, phenylpropanolamine, has been the subject of a recent study by a professional committee, and their recommendations to the Agency are that the drug continue to be made available for over-the-counter use in the kinds of drug products that it has been traditionally used in over the last number of years at the levels that are currently found in those products. Therefore the Agency is faced with a dilemma with the legitimate use for these products, being confirmed at least at the present time by a panel of experts and, on the other hand, a growing concern over the street trafficking of these drugs.

So, somewhere over the next couple of months, those two issues will have to merge. If the evidence becomes strong enough to support scheduling action, an administrative action, one open to challenge in the courts, then we would make this kind of recommendation.

We are not prepared yet to make a recommendation that any one of these drugs in the OTC look-alike area should be scheduled under the Controlled Substances Act.

Mr. GUARINI. We are talking about the pharmaceutical companies and others that have their impact on the State and Federal legislature and all the administrations.

Well, how is the public interest being protected? Is there an ongoing investigation concerning PPA, caffeine, and amphetamines, and all these other analgesics that are really the subject matter of our hearing today.

Are they considering looking into diet pills and pep pills and the things that the FDA allows people to ingest and take into their system?

Mr. HILE. There are two parts to the answer to that: The Agency has a continuing responsibility to review drug experience, not only look-alikes, but look-alikes would be included in that; and as evidence is gathered, it is regularly reviewed, and decisions are made whether or not that balance is reached, whether or not that drug has become a drug of abuse.

This is a continuing, ongoing function of the agency. To the extent that we can regulate the current OTC look-alike problem, with our existing statute, that is a continuing investigation for the agency, and we will continue to bring what actions are available to us.

Mr. GUARINI. Is anything being reconsidered by the agency now, or is it an ongoing, continuing investigation?

Mr. HILE. I am sorry?

Mr. GUARINI. Is the Agency reconsidering allowing these substances to be openly pushed to the public? Is there a reconsideration of that decision?

Mr. HILE. It is a continuing matter but in each instance it would be reconsideration. Decisions have been made in the past that the drugs can be made available over-the-counter.

Mr. GUARINI. Mr. Haislip, are narcotic pushers getting into the pep pill business at all? Are there street people that are pushing these in our high schools and colleges?

Mr. HAISLIP. If you are speaking now about amphetamines and stimulants that are under our Controlled Substances Act, the answer definitely is yes. It is one of the major components of the drug problem. There are controls over these drugs already.

We arrest a lot of people for trafficking in them, not enough obviously, but we do arrest a lot, so there is no question about it being a major part of the problem.

Mr. GUARINI. Is the underworld involved in this, the seedy part of our society?

Mr. HAISLIP. I am speaking now of the amphetamines and major stimulants, not the look-alike products which are designed to look like them. The look-alike products are a little different. We don't believe that the major drug traffickers are dealing with the so-called look-alike products. They are dealing in the real thing.

Mr. GUARINI. Is the end result the same? We are talking about a method compared to substance. In substance, it is the same thing. They are actually making money selling at high profit, similar kinds of drugs which is causing a health hazard?

Mr. HAISLIP. It is similar, not identical.

Mr. ZEFERETTI. Would you yield to me?

Mr. Tobin, you are the District Representative of DEA. Could you tell us in response to his questions, how do you get involved on a local level with this overall look-alike drug situation. Mr. Haislip seems to be directing most of the attention to the controlled substances, anyway.

Mr. TOBIN. I will try to answer both parts. I believe, as Congressman Guarini said it, there probably are people who dealt with illicit drugs in this business. Whether it is illicit or licit drugs, people do it to make money, not to sell drugs.

I am a representative of a DEA field office here in New Jersey, and I just feel that my hands are completely tied. I can only enforce the Controlled Substances Act. In regard to look-alikes, there is no violation that I can see of the Controlled Substances Act.

I can talk to people, but I can't do anything. If I had a law, I could do something, but I don't have a law.

Mr. ZEFERETTI. Have you done anything within the local area to educate the people with what it is that they are buying, or what a look-alike drug is? Have you done anything to inform people about look-alike drugs?

Mr. TOBIN. Yes, I have. Every opportunity I have had, I have talked to groups and so have my training officers. Last week I was at Essex County Boy Scout Council, and explaining the dangers of look-alikes.

Maybe there is an answer, as far as prosecuting someone who causes an injury. I can only deal with the Controlled Substances Act, and there is no violation.

Mr. GUARINI. Mr. Chairman, I understand that the Federal Trade Commission, which is in charge of unfair trade practices, is submitting a statement for the record and will have it available, which would complement everything that has been said here.

One last question, I understand there is interagency cooperation among FDA, DEA, et cetera. Has that been put into an interagency task force where you are really working together as a team, or this is a loose conglomeration of relationships between you?

Mr. HAISLIP. We do not have something that you would call a task force working together at that level.

Mr. GUARINI. Don't you think it would be helpful to have some kind of formalized task force to give you a better sense of communication among yourselves as to what is needed?

Mr. HAISLIP. It is our intention, I believe, to continue to coordinate and exchange the information, and if indeed we see that there is something to be gained by structuring that tighter, then we will do that, certainly.

Mr. GUARINI. We are here to find a solution to the problem. I am surprised we have not gotten to that point of formalizing a closer line of communication among all of you, and initiatives should be taken whereby you would have an interagency task force to concentrate on the problem, instead of having an exchange of telephone calls.

Mr. HAISLIP. It is not going to be loose or ineffective as far as authorities. We are all dedicated to working together. Speaking for DEA, I am certainly not going to conclude—well, we want to see what effect our actions will have.

87-601 O - 82 - 3

The actions we are taking really deserve a great deal of praise, and they may indeed have a great deal of effectiveness. It is not clear yet. I say this sincerely, given the vast array of problems we have to deal with, I don't think that this is a case where we have been caught seriously behind, not this time.

With regard to the paraphernalia and the headshops, that maybe, but this time we are a little bit more alert to the developments than is often the case.

Mr. GUARINI. Let me just say that this problem has grown from a few shops to 110 or 120 companies within a very, very short period of time, and it does not take much of a mathematician to know if we don't get on to the subject matters immediately, it will get out of hand. The time to really stomp it out is now, and not to wait until it gets to be a big national problem like narcotics and hard drugs are.

I would suggest that we don't wait for the problem to develop, that we get together an interagency task force and be able to have some preventive law, and do what we can immediately without delaying the subject.

Mr. HAISLIP. I am in complete agreement with you, sir.

Mr. MURPHY. I would like to echo Mr. Haislip's comments. It is true we do not have a formalized task force approach, but we are cooperating with the other agencies.

I know that the FDA's actions were coordinated with some of our actions, and I think if there is a need for something tighter, we can look at it and consider it at that time. But right now, we have a working relationship.

Mr. GUARINI. Maybe I am less patient with Government than you are, but I see our whole narcotic problem in so many different hats that I just wonder whether or not we are effective as a Nation in combating it.

I see our foreign trade problem with so many bureaucratic agencies having control, and with so many different departments having fragments of it, that we don't have as effective a foreign trade program that we should have and this attitude holds us back, because Government is so big that it gets out of control.

If we are serious enough about finding a solution to a subject matter, there is nothing wrong with saying that we are going to sit down and have closer communication and put all of our strength together and not wait for 2 or 3 years to get the subject matter taken care of.

Mr. MURPHY. I do think that we are sitting down, and I am sure we will continue that.

Mr. HILE. I would like to add, so that the record is complete, certainly to the extent that our activities can be formalized to a greater extent than we have in the past, there is not one of us that would not move to do that.

We will keep that in mind and do the kinds of things that are necessary to assure coordination and cooperation. To the extent that we have been coordinating, I would like to point out that the seizures that the FDA made in the nine manufacturing establishments were coordinated with the Post Office Department, and they filed all of their actions on the same day and that was all coordi-

nated so that the action against all the manufacturers and distributors was done on a single day, and that took a major effort.

We also had to coordinate with the U.S. Marshal Service and with the U.S. attorneys and Justice Department in order to accomplish the seizures.

Mr. GUARINI. While you were so effectively addressing yourself to the nine in that period of time, another 100 cropped up. That is the problem I am trying to get to. It is not a matter of having some effective course of action, but it is a matter of taking all your joint talents and experiences and energies and putting them together where we can really get a program for our country that would be in the best interest of our consumers and the health of our people.

Mr. ZEFERETTI. Gentlemen, we want to thank you for your contribution this morning, and I hope we can continue to have the dialog that we have had in the past. If we find that there are questions that we would like to submit to you for further examination, I would hope that you would respond to this committee in writing.

Thank you so very much.

[A position paper of the Federal Trade Commission was submitted for inclusion at this point.]

PREPARED STATEMENT OF TIMOTHY J. MURIS, DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION

Mr. Chairman and members of the select committee, this statement is in response to your request for my views on the subject of so-called "look-alike" drugs. My remarks are only the views of a member of the Commission staff, and are not intended to be, and should not be, construed as representative of official Commission policy. To this traditional disclaimer, I must add one of my own. I only recently arrived at the Federal Trade Commission, having assumed my present position on October 5, 1981. In addition, the matter of first priority was necessarily evaluating the FTC's budget in response to the President's recent proposals and to Congressional inquiries regarding these proposals. Until the end of last week, my involvement in review of the agency's budget required most of my attention, limiting severely the available time for evaluation of other issues. For these reasons, I am not yet intimately familiar with the issues before you.

The staff of the Federal Trade Commission has begun to study the over-the-counter drugs called "look-alikes." By "look-alike" drugs, I mean tablets or capsules that contain ingredients available over-the-counter but resemble certain prescription drugs that are subject to misuse. In addition to their physical resemblance, sellers of these products frequently promote them as providing the same effect on the user as their prescription counterparts. Some advertisements even promise a "legal high," and refer to the products being sold as "legal dexies, yellow jackets, and black beauties"—all street names for prescription drugs that can be abused. The nature of these products, their physical appearance, and the manner in which they are sometimes advertised suggest a potential for consumer injury.

The "look-alike" trade is burgeoning. Although the total volume of the "look-alike" business is unknown, these products appear to be produced and sold in large quantities. For example, I understand that approximately 23 companies fill capsules or make tablets in the Lewistown, Pennsylvania area alone, one of the major areas where such drugs are produced, and the two largest purportedly ship a total of a quarter of a million "look-alike" tablets per week.

The sale of "look-alike" drugs raises issues of concern to those involved in developing and implementing public policy. Although the ingredients in question are available over-the-counter, their misuse can cause serious physical injury, even death. To study this issue, the staff of our Division of Food and Drug Advertising recently completed a preliminary investigation. We have provided the Committee with a copy of this staff recommendation. Some staff members are presently inclined to recommend that the Commission authorize the opening of a formal investigation and the issuance of compulsory process. The Division's recommendations are still under review within the Bureau, however, and have not been forwarded to the Commission. Thus, the Commission has not addressed "look-alike" drugs.

The recommendation that staff has prepared is based on a preliminary investigation. During this stage, staff members gather basic facts about a possible problem. These facts are then analyzed in terms of the need for and appropriateness of Commission action. Before further resources are spent on this matter, both the Bureau and the Commission must give their approval.

In deciding whether to support the Division's recommendation, I will be conducting a thorough review of the proposed investigation. One of the issues that I anticipate raising is whether, given the Commission's limited resources and the available remedies, Commission action would result in a significant reduction in harm. The Commission's authority in this area is generally limited to the issuance of administrative complaints and ultimate entry of cease and desist orders. Further analysis may reveal that the atomistic structure of this industry renders meaningful relief by the Commission difficult to obtain. Moreover, if the essence of the problem is drug abuse, the solution may not lie in the FTC's regulatory remedies. Of course, we will continue consulting with other appropriate state and federal agencies to determine if other enforcement approaches are more promising. Given the complexity and variety of issues raised, much additional thought is necessary before a conclusion can be reached.

I would like to emphasize my concern with this issue and my intent to devote further serious study to the staff's proposed investigation. Public inquiries such as this one will both focus attention on the potential means of dealing with this issue and help define solutions.

Mr. Harold Ruvoldt and Mr. Joseph Falcone, please come to the witness table.

You may proceed with your statements.

Identify yourselves and proceed in any way that you feel comfortable.

TESTIMONY OF HAROLD J. RUVOLDT, JR., PROSECUTOR, HUDSON COUNTY, N.J.

Mr. RUVOLDT. I am Harold Ruvoldt, Jr.

I have already supplied the committee with my formal statement which I understand will be incorporated in the record.

I want to thank you for the opportunity to be here, and I appreciate very much your staff's invitation to me as well as the preliminary discussions I had with Congressman Guarini.

There are two points which are a little different than what most of the witnesses will emphasize which I would like to dwell on now.

One is the fact that under our present law in New Jersey it is extremely difficult to successfully prosecute the type of violation that the look-alike drugs present.

The problem is complicated by the fact that there are at least two provisions in our statute, one which seems to make the use of counterfeit drugs, or so-called beat bags, in the normal narcotics transaction, illegal.

The second problem, however, is that it is extremely difficult to successfully prosecute, since the witness who is the victim of the fraud, if you will, is usually the one who is acquiring or believes he is acquiring illegally the controlled dangerous substance, so that the quality of the State's evidence is weak.

New Jersey is presently contemplating passing a bill to address this problem, so that may be a step in the proper direction.

Our information has led us to believe that most of those transactions take place through the use of mail, and mail orders. In Jersey City in the shadow of the courthouse, a concern presently sells look-alike drugs which are advertised as stimulants and sleep-aids. They claim to be the strongest product on the market, and they are

physically designed to appear like a controlled dangerous substance.

Their advertisements, order blanks, would lead one to believe they are in fact CDS, and yet the products themselves are not.

The end result of this is to distribute within a community a large amount of products which drain law enforcement efforts and do it through transactions which are somewhat insulated from local law enforcement techniques.

It is the manufacturer, the distributor, who is at the heart of the problem, and only through Federal legislation would directly address that type of mail order business, phone order business, do we believe that we can effectively do something to prevent this type of activity.

The last point, there is a tremendous drain of manpower, of normal law enforcement manpower that these types of drugs take. An analysis of the activity by our chemical laboratory over the past year indicates in excess of 10 percent of our man-hours are directed toward the analysis of this type of product, which is not a controlled dangerous substance, so you have laboratory time, agents in the field who are led to believe and indeed may conduct substantial investigations as a result of look-alike drugs, and in fact not be pursuing the source of controlled dangerous substances.

This demand of manpower necessarily draws away from police activity aimed at illegal conduct which should be properly the prime target. We do believe that through substantial Federal legislation directed at manufacturers and distributors that the problem can be curtailed.

Thank you.

[The prepared statement of Mr. Ruvoldt follows:]

PREPARED STATEMENT OF HAROLD J. RUVOLDT, JR., PROSECUTOR, HUDSON COUNTY, N.J.

I wish to express my gratitude to the Chairman and to the House Select Committee on Narcotics Abuse and Control for giving me the opportunity to express my views on the problem of "look-alike" drugs.

As the Chief Law Enforcement Officer of the County of Hudson, responsible for the enforcement of the criminal laws of the State of New Jersey in this jurisdiction, I am greatly concerned about the ever increasing use and misuse of all types of drugs, and I see the advertisement, distribution and use of "look-alike" drugs as a part of that overall problem.

America presently is afflicted with an epidemic of drug-related problems. I have personally seen the ready availability of the so-called "hard" drugs on the streets of Hudson County as evidenced by the numerous seizures made by the Narcotics Strike Force of my office and the local police departments throughout the county. The Prosecutor's Office is committed to the eradication of the illegal narcotics trade in Hudson County, and I have committed a large segment of investigative personnel and employed every investigative resource available, including the use of electronic surveillance, to attack not only the street pusher, but also the upper echelon of the narcotics trade. Those who traffic in drugs in Hudson County are on notice that should they do business in this county and be caught, not only will they be vigorously prosecuted, but also the toughest sentences will be sought upon their convictions.

However, America's drug epidemic goes beyond the use and distribution of the "hard" drugs, such as heroin, LSD, and cocaine. It has been estimated that seven million Americans use "legal" drugs such as barbiturates, tranquilizers and amphetamines for non-medical purposes. Likewise, it is estimated that as many as seven out of every ten drugs being abused or resulting in death are legal drugs. There is little doubt that America is a society dominated by and highly susceptible to the appeal to drug use. One only need to look to the communications media to see how deeply this society has become involved in drugs. Drugs are advertised as the cure

for every physical and mental problem, ranging from insomnia to obesity. The basic media pitch is that any and all problems can be solved by taking a pill or swallowing a capsule.

With this background in mind, a situation that is appearing more frequently in the State of New Jersey, especially in the urban areas of this State, is the distribution of the so-called "look-alike" drugs such as caffeine phenylpropanolamine and ephedrine. At this time, the major emphasis of the Prosecutor's Office is on the prosecution of the distribution of the hard drugs. This emphasis exists not only because of the greater injury potential associated with those drugs, due to the fact that in Hudson County there exists a larger number of distributors in controlled dangerous substances, and also due to the fact that drugs are a root cause of many street crimes of a more violent nature.

However, this is not to say that the increase in the use and availability of the "look-alike" drugs is not of concern to my Office, and I see a number of problems with these "look-alike" drugs. Problems which are on an increase in our County.

(1) The ready availability of the drugs. These drugs are frequently advertised in nationally circulated periodicals. The advertisements are frequently misleading and encourage not only the use, but also the distribution of the drugs. Also, the drugs are usually distributed by mail, frequently from out of state.

(2) Appearance of the drugs. The "look-alikes" are so called because they are manufactured to resemble barbiturates and amphetamines. For law enforcement personnel, the deceptive appearance presents a variety of problems. For example, in the situation where an undercover agent makes what he believes to be a "buy of an amphetamine or barbiturate, but later discovers the substance he bought was not a controlled dangerous substance, but was in fact a "look-alike" drug, under present New Jersey Law, there is no violation of the narcotics law for which the seller could be prosecuted, albeit prosecution for theft by deception, while complex, may be possible.

(3) The fraud potential. Frequently, "look-alike" drugs are obtained at a relatively inexpensive price on the wholesale level, only to be distributed by the buyer at a price ten to twelve times greater than the wholesale price. Many times the buyer advises his potential buyers that the "look-alike" was in fact something it was not; e.g., barbiturate or amphetamine. Although the monetary loss to the potential buyers due to the misrepresentation of the buyer is not of great concern to law enforcement, since the potential buyers thought they were buying illegal substances, the unjust enrichment of the buyer, due to misrepresentation, would concern law enforcement since there is no drug law that prohibits or restricts such activity.

(4) The manpower drain. Drugs appearing to be controlled dangerous substances are estimated to take an estimated 10 percent of the time of the Narcotics Strike Force.

(5) The safety of the drugs. The three predominant "look-alike" drugs are caffeine, phenylpropanolamine and ephedrine. As to caffeine, although there has been no recorded case of death from caffeine overdose, doses of more than ten grams ingested orally have induced convulsions. Further, caffeine doses of more than 250 milligrams have been known to induce cardiac irregularities. Although fatal poisoning is extremely rare, children have been known to be very susceptible to caffeine toxicity.

As to phenylpropanolamine (PPA) it is a "look-alike" drug related to ephedrine and amphetamine and causes weak central nervous system stimulant action. PPA has been known to have several adverse side effects, including nervousness, headache, nausea and palpitations and excessive rise in blood pressure.

(6) The juvenile problem. Perhaps the greatest problem with "look-alike" drugs is the danger to the young people of this country. Although there is much debate regarding the safety of these drugs, their easy availability and non-restrictive nature possess great potential to encourage juveniles to experiment and use drugs and also to distribute these drugs. The misleading advertisements make it appear that there is little, if anything, wrong with the taking of these drugs. The danger lies in the drug concept itself. If the user is not satisfied with the "high" he receives from the "look-alike" drug, the user may very well turn to illegally obtained prescription drugs or even to controlled dangerous substance.

At present, there is very little the Prosecutor can do legally to combat the spread of these drugs. In New Jersey, it does not appear to be criminal to distribute "look-alike" drugs, if clearly identified as such. Likewise, there is no Federal Law that prohibits such distribution. There is a proposed bill in a Senate Committee of New Jersey that would make it a violation of the controlled dangerous substances law of New Jersey for a person to "agree, consent, offer to sell or give a controlled dangerous substance to another person and in turn sells, gives or delivers a non-controlled dangerous substance in lieu of the controlled dangerous substance." The proposed bill would make such activity a crime of the third degree. In essence, the

bill would make the agreement to sell any controlled dangerous substance and the later substitution of another material for that controlled dangerous substance a crime punishable by between 3 and 5 years imprisonment and by a fine of not more than $7,500 or both. This bill (Senate Bill No. 512 sponsored by Senators Gregorio and A. Russo) addresses the problem with the undercover street buy that results in a finding of non CDS.

However, this bill is limited in its scope and does not address the broader problem of the interstate mail order distribution of "look-alike" drugs.

The solution to this problem in my opinion will come only from a united effort on the Federal, State and Local levels to not only attempt to restrict the distribution of these drugs, but also to alert the public as to the possible dangers of these drugs.

There have been efforts on the State level to impose criminal penalties on distribution of "look-alike" drugs. In Delaware, it is unlawful for any person to knowingly deliver or attempt to deliver a non-controlled substance upon either (1) the express or implied representation that the substance is a narcotic or non-narcotic controlled substance; or (2) the express or implied representation that the substance is of such nature or appearance that the recipient of said delivery will be able to distribute said substance as a controlled substance.

This law establishes that it is prima facie evidence of the implied representation if any two of three factors are established: (A) the non controlled substance was packaged in a manner normally used for the illegal delivery of controlled substances, (B) the delivery or attempted delivery included an exchange of or demand for money or other valuable property as consideration for delivery of the substance, and the amount of such consideration was substantially in excess of the reasonable value of the non-controlled substance, (C) the physical appearance of the finished product containing the substance is substantially identical to a specific controlled substance.

In Illinois, the Attorney General of the State of Illinois has recently filed suit against a "look-alike" drug distributor based in Maryland. The suit alleges various violations of the Illinois Uniform Deceptive Trade Practices Act and Consumer Fraud. The Attorney General sought to have the Maryland distributor enjoined from distributing "look-alikes" in the State of Illinois.

There are examples of the state's response to the "look-alike" problem. However, it appears to me that without Federal action to restrict, hinder or stop the interstate flow of "look-alike" drugs, actions on the State level will be fruitless. This action could include regulation regarding the size, shape and appearance of these drugs, restrictions on misleading advertisements, age restrictions as to whom these drugs are distributed.

Finally, there needs to be a greater awareness on the part of the public at large both as to the existence of and the potential dangers of "look-alike" drugs, especially as it pertains to the younger segment of our society. The "look-alike" drug problem is only a part of the greater drug problem facing American society. If the attack on the use and abuse of all types of drugs started in the homes of America, and the youth of America were aware of the many dangers that are present with the uncontrolled abuse of drugs, the law enforcement community would be one step closer to solving and eliminating the drug epidemic in the United States.

TESTIMONY OF JOSEPH A. FALCONE, PROSECUTOR, PASSAIC COUNTY, N.J., ACCOMPANIED BY FIRST ASSISTANT PROSECUTOR JOHN P. GOCELJAK, AND DETECTIVE LAURENCE LOUGHLIN

Mr. FALCONE. I am Joseph Falcone. I am the Passaic County prosecutor. With me today is my first assistant prosecutor, John Goceljak, and on my far left is Detective Laurence Loughlin.

I would like to thank the chairman and the members of the committee for affording me this opportunity to appear today.

Right now in New Jersey it is rather simple for someone to obtain a certificate of registration and to engage in the wholesaling of these kinds of drugs.

In New Jersey we fill out an application, pay a $100 fee, and a certificate is awarded.

As I pointed out in my statement, there is no background examination done of the applicant, and the example I gave of the person,

the husband of the applicant had previously been convicted of narcotics offenses in this State, and yet they are able to, the wife was able to, by merely going through this simple pro forma type of procedure, obtain a certificate of registration; and under our present state of the law, the court had to and we had to go along with it, much to our dislike.

The return of some 37,000 caffeine pills to that person——

Mr. ZEFERETTI. Certificate of registration to do what?

Mr. FALCONE. To engage in the wholesaling of these kinds of drugs, the drugs not deemed to be controlled dangerous substances.

I have brought this matter to the attention of the Attorney General's office in the spring of this year, and received some memoranda which went back and forth between various sections of that office, and I am under the impression that some amendatory legislation is being contemplated by the department of health in this State to try to combat this particular problem.

Right now in New Jersey, particularly in law enforcement, we have a resource problem.

Economics have forced many offices, including my own, to have to cut back in the personnel that we have. In 1980 my office was reduced by 22 percent by virtue of economic problems. That meant I lost 33 people, and if I have to devote what is left to this kind of problem, it makes it very difficult. At the local level it is also difficult for police departments who yearly are being reduced due to economic problems to deal in an effective way. And, it is that much more difficult when we have no specific legislation on the books to enable us to effectively deal with the problem.

There is presently pending a piece of legislation that the county prosecutors association, in conjunction with the Attorney General's office, has prepared and wants to have some legislator at the State level introduce.

This past Thursday I attended a meeting, and those in attendance unanimously agreed that we would recommend to the entire delegation that we wholeheartedly support this bill.

This is a bill which is patterned after legislation in States like Delaware and Maryland which would give us some teeth which would enable us to effectively deal with the problem and impose appropriate sentences both in terms of custodial time and more appropriate a rather heavy fine for violations of that particular section.

Mr. Ruvoldt also pointed out, and I agree, there has been a tremendous drain on our laboratories by virtue of having to analyze what turns out to be drugs that are not CDS. We have what I consider to be a very effective speedy trial program, but one of the things which impedes our ability to maintain an effective speedy trial program is the delay caused by the backup in our laboratories.

This backup is exacerbated by the non-CDS drugs having to be analyzed by those laboratories.

I am subject to your questions.

[The prepared statement of Mr. Falcone follows:]

PREPARED STATEMENT OF JOSEPH A. FALCONE

The problem with so-called "look-alike drugs" in New Jersey is exacerbated by the ease with which a person may obtain a Certificate of Registration from the New Jersey State Department of Health. The following example graphically illustrates this problem.

In August 1979, members of the West Milford Police Department, armed with a search warrant, entered the premises of Mark and Daria Werner located at 28 Tansboro Road, Hewitt, New Jersey. Pursuant to the warrant a search was conducted. A seizure of cocaine and other C.D.S. was made. Mark Werner was charged and ultimately pled guilty to the Unlawful Possession of C.D.S. He was given a six-month sentence to the Passaic County Jail.

On March 28, 1980, the West Milford Police, again armed with a search warrant, entered and searched the Tansboro Road premises of Mark and Daria Werner. The Police found and seized some suspected marijuana, some unidentified white powder (which ultimately proved negative for C.D.S.), $1,162.00 in cash and 37 large plastic containers, each containing 1,000 caffeine pills. At the time of the search and seizure only Daria Werner was at home. She explained to the police officers that she was holding the pills for a friend whose identity was unknown to her.

On Monday, March 31, 1980, Daria Werner went to the New Jersey State Department of Health in Trenton to obtain a drug Certificate of Registration. (Daria Werner was accompanied by a male named Eric when she went to the State Department of Health. He, too, completed and filed a registration statement and obtained a Certificate of Registration in the name of D&E Health (ostensibly Daria and Eric). Eric, who is known to the West Milford Police, has engaged in activity similar to Mark Werner and is apparently advertising through printed cards the availability of these pills; there is no reference in the advertisements that the pills are caffeine pills). Her application was made pursuant to N.J.S.A. 24:6B–1 which provides that "no person shall hereinafter engage or continue to engage in a drug manufacturing business or a wholesale business in this state without first filing a completed registration statement with the department."

Daria Werner filled out a registration statement. The registration statement filed by her indicated (1) that the trade name or name under which the business will be conducted is D&M (ostensibly Daria and Mark), (2) that the location of the business is 28 Tansboro Road, Hewitt, New Jersey, and (3) that the actual business to be conducted will be the wholesale manufacture of over-the-counter drugs. After filling out the registration statement and paying the $100.00 fee, Daria Werner was issued a Certificate of Registration.

Prior to the issuance of the Certificate of Registration no one at the State Department of Health conducted a background examination of the applicant. No one at the State Department of Health checked to see whether criminal activity of any kind had ever been uncovered at the subject premises. In fact, the applicant is not even required to take an oath that the person or persons named in the registration statement are the only ones associated with the company or corporation.

On June 10, 1980, Mark Werner, through his attorney, filed a civil action to recover the 37,000 caffeine pills and the $1,162.00 in cash which had been seized pursuant to a valid search warrant. This action was predicated on the theory that the pills (and the cash which was the proceeds from prior sales of the pills) were possessed as part of a legitimate drug wholesaling business which is conducted pursuant to a Certificate of Registration issued by the New Jersey State Department of Health.

My office filed an Answer in opposition to the relief sought by Mark Werner. In August 1980, the Court entered an Order returning the $1,162.00 since the State could not show to the Court's satisfaction that the money was related to the drugs in question. We did not contest this ruling since laboratory tests of the suspected white powder were negative for C.D.S. and since there was no evidence that the money was related in any way to the caffeine pills.

On April 16, 1981, the action involving the return of the 37,000 caffeine pills was heard before the Honorable Thomas R. Rumana, J.S.C. During the hearing we presented as a witness Mr. Lucius A. Bowser, Acting Chief of the Drug Control Program of the State Department of Health. It was Mr. Bowser who had issued the Certificate of Registration to Daria Werner on March 31, 1980. According to his testimony the department has no discretion with regard to the issuance of a Certificate of Registration; once the registration statement is completed and the fee paid, the Certificate of Registration is issued. Once the Certificate of Registration is issued, the applicant is free to engage in the manufacture or wholesaling of drugs. (The drugs referred to are not C.D.S. The drugs we are concerned with in this

matter are those which are defined in N.J.S.A. 24:1-1, and which are regulated by N.J.S.A. 24:6B-1 et seq.)

We also presented as a witness at the Hearing West Milford Detective Laurence Loughlin. Detective Loughlin explained that these caffeine pills are obtained from a manufacturing firm in Pennsylvania which caters to this growing trade. Apparently, this manufacturer will manufacture caffeine pills to order (e.g. different colors, sizes, shapes, etc.) to simulate various other drugs which are only lawfully obtainable with a doctor's prescription. These caffeine pills, disguised as "uppers" are then sold to youngsters at a cost of $.50 to $1.00 per pill. According to Detective Loughlin these pills are then ingested by the youngsters who may then get a psychological lift and to some extent physical stimulation from the concentrated caffeine. Detective Loughlin also indicated his belief that Daria Werner and/or Mark Werner are not conducting a legitimate wholesale business. Detective Loughlin opined that the caffeine pills are being sold in small quantities either directly to students and other young adults, or to other individuals who in turn peddle the pills to students and others.

At the conclusion of the hearing, Judge Rumana directed the return of the 37,000 caffeine pills to the plaintiff, Mark Werner. Judge Rumana commented that the statute, as presently written, left him no alternative. He noted that anyone, including someone with a prior criminal record could obtain a Certificate of Registration merely by completing and filing the requested registration statement and paying the statutory fee. Since the Werners were in possession of a Certificate of Registration, and since we were unable to prove that they were engaged in activity other than the wholesaling of pills, there was no justification for the seizure.

As the statute (N.J.S.A. 24:6B-1 et seq.) is presently written, anyone can obtain a Certificate of Registration merely by completing the registration statement and paying the required fee. No criminal background investigation of the applicant is conducted by the State Department of Health. No inspection of the proposed business location is made by the State Department of Health. (Detective Loughlin described 28 Tansboro Road as a small one-family residence situated at the end of dirt road in a relatively remote section of the Upper Greenwood Lake area of West Milford. While it is apparent on the surface that the legitimacy of any drug wholesaling business at or from these premises is dubious, Mr. Bowser testified that there is no requirement that the applicant elaborate as to the location or that the State Department of Health inspect same. Mr. Bowser referred to one applicant who has obtained a Certificate of Registration even though he operates through a Post Office Box number and not from a specific building location).

It is apparent that the local police, members of my staff and the State Department of Health are frustrated with regard to dealing with this situation. On May 6, 1981, I brought this problem to the attention of the Attorney General's Office of the State of New Jersey. Upon a review of the statute in question and Assistant Deputy Attorney General concluded, "The Department of Health presently does not have the authority under N.J.S.A. 24:6B to consider prior criminal background or to deny a registration certification to any person filing a completed registration statement to engage in a drug manufacturing business in this state unless that business involves C.D.S." Although the Department of Health is opposed to making a criminal background check a requirement for registration since the vast majority of drug manufacturers are in their view reputable, I have been advised that they are considering model legislation to address the problem I brought to their attention.

The Legislative Committee of the New Jersey County Prosecutors Association, of which I am a member is presently reviewing proposed legislation to deal with the problem of "look-alike" drugs. This proposed legislation, modeled after statutes enacted in other states, was prepared by Deputy Attorney General James Morley. As presently written this legislation (a) prohibits manufacturing of "look-alike" drugs, (b) prohibits distribution or possession with intent to distribute under certain circumstances suggesting an attempt to pass "look-alikes" off as the real thing, (c) preempts mistake of fact as a defense, and (d) establishes a maximum penalty of three years in jail and/or a $100,000.00 fine. In my view, enactment of this statute into law will assist in dealing with this problem. However, federal legislation is also necessary since the problem is one of national magnitude.

I would like to thank the members of the Committee for affording me the opportunity of appearing here today. I trust that your concern will lead to much-needed legislative initiatives in this area.

Mr. ZEFERETTI. Thank you, sir.

How serious do you feel the look-alike problem is in this particular county or in New Jersey in general?

Mr. RUVOLDT. It is extremely serious because of the quantity, the easy access to New York, and the look-alikes that we find most frequently with the younger people.

That is primarily because they lack the sophistication of the drug culture to identify them.

Indeed, they are made so that even a trained chemist on appearance without analysis would seem to think they are a fact.

Mr. ZEFERETTI. Is there a public awareness of the magnitude of this problem?

Mr. RUVOLDT. Not really. I think it is tremendous that this committee would come here to hear this type of testimony.

The public generally is unaware that this is a serious problem. They are unaware of the fact each of these drugs has in and of itself serious side effects, and the public is unaware of the degree which this is a drain on manpower.

Perhaps the committee, by being here, can emphasize the fact that there are such enormous quantities, jars 2, 3 feet high which would appear to be amphetamines, and these find their way onto the streets and they are passed around and sold as if they were controlled dangerous substances.

It is critical that the public be made aware that something must be done about it.

Mr. ZEFERETTI. Were you here when the other gentleman testified?

Mr. RUVOLDT. No; I was not.

Mr. ZEFERETTI. We had asked a number of times whether or not there was a task force that had been put together to share intelligence and share what they might think would be some of the tools that we could use to combat this problem.

Do you people meet in any kind of a task force where you share information?

Mr. RUVOLDT. No; we do not. The information as to location is not atypical. We received in the last week in the mail an order blank addressed to one of our employees for the ordering of these substances.

I have it with me as well as the card that they circulated. Access to information is not too different at all.

Mr. ZEFERETTI. Only under consumer fraud?

Mr. RUVOLDT. Theft by fraud, and there is a very weak possibility under a counterfeit provision of the controlled dangerous substance law, but it is the type of crime which the distributor can say he is not misrepresenting his product. He does not purport it to be a controlled dangerous substance.

The crime of fraud actually occurs when the substance is broken down into small packages and sold illegally on the streets. Where a product which sells for $50 to $1,000 may sell for $5 a pill, that is actually committed.

I know, having read over the weekend the statements of the U.S. Attorney General about the involvement or the thrust of the Federal Government toward more active participation in the area of crime, it was suggested that contract murder be made a Federal crime; but this is an area which is a lot less glamorous than contract murder, but more at the root because of our problems.

It is an area where it's uniquely suited for Federal prosecution.

Mr. ZEFERETTI. We share your concerns and we share the problems of cutbacks as far as the restraints we have had on the budget. We found ourselves cutting back in the very same areas that we set up as instruments to solve the problems, such as Customs. Now we find ourselves hamstrung at this particular time as far as manpower and budgetary kinds of constraints.

Mr. Loughlin, how do you get involved? Is it a mixed bag when you are out on the street? Do you find yourself going after the controlled substances and instead getting look-alike drugs?

What type of situations do you meet up with in your area?

Mr. LOUGHLIN. In the incidence that we mentioned before where 37,000 pills had to be returned, I came into possession of those when I executed a search warrant at a house where we had had two controlled purchases of marihuana from that residence; and when we executed the search warrant, we came up with pills hidden in a garbage dumpster behind the house as well as in open bags on the bedroom floor.

The house that they were being wholesaled from was littered with dirty clothes, debris throughout the house, and outside the house were wrecked cars, used boats, and not what you would call a sanitary condition at all.

This is what they call their wholesale operation, and also this house is located back up in the woods, not in a formal location where people would come in to purchase on a wholesale basis.

Mr. ZEFERETTI. Actually, when you find that, they can't prosecute if the drugs are not sold?

Mr. FALCONE. Yes, if they are wholesaling, then they are within their rights pursuant to the certificate of registration that they obtained.

Mr. ZEFERETTI. They are given a summons if they don't have the certificate?

Mr. FALCONE. Correct. There is no teeth right now in the law, as Mr. Ruvoldt pointed out.

Mr. ZEFERETTI. Is there anything in the State food and drug laws that could be put together that might bring about a criminal prosecution that you would like to recommend?

Mr. RUVOLDT. I would like to recommend that you give serious thought as to whether or not it should not be a Federal crime to manufacture or distribute drugs which take on the appearance, size, shape, and are sold without a clear indication as to what their content is.

One of the drugs, it was a heart-shaped drug, and for a manufacturer to go to the trouble to reproduce the color, shape, form, and mode of appearance and to advertise it as a stimulant, and if that isn't, nothing more is in and of itself the beginning of a fraud.

Regardless of how deeply you want to dig into the literature, you will find very little if any justification for the manufacture and distribution of this type of drug other than to facilitate street crime.

Mr. ZEFERETTI. That is outlandish to me. There is no doubt about what the distributors are trying to do.

Mr. RUVOLDT. They do it with business cards. On the back side of this you can see the different types of amphetamines, the black

beauties, and on the front side you see the other types of tranquilizers, and I would defy any chemist to look at them.

They not only reproduce the shape and size but two types of amphetamines with different types of scoring on them, and they reproduce that scoring on the drugs.

There can be very little doubt that the intent is to produce an appearance that would successfully deceive someone not conversant with chemical analysis.

Mr. FALCONE. I understand we have a representative of D. & E. Pharmaceuticals who will be testifying. I have a copy of their business card which if you would like I would leave with the committee. It contains pictures of all the various drugs and it says on the bottom, "Sales of Uppers and Downers."

I have a newspaper article, the September 27 edition of the Argus, printed in the West Milford section, and that same company had a truck with advertising on it which indicated what they have for sale, and so forth.

I would make that available to the committee.

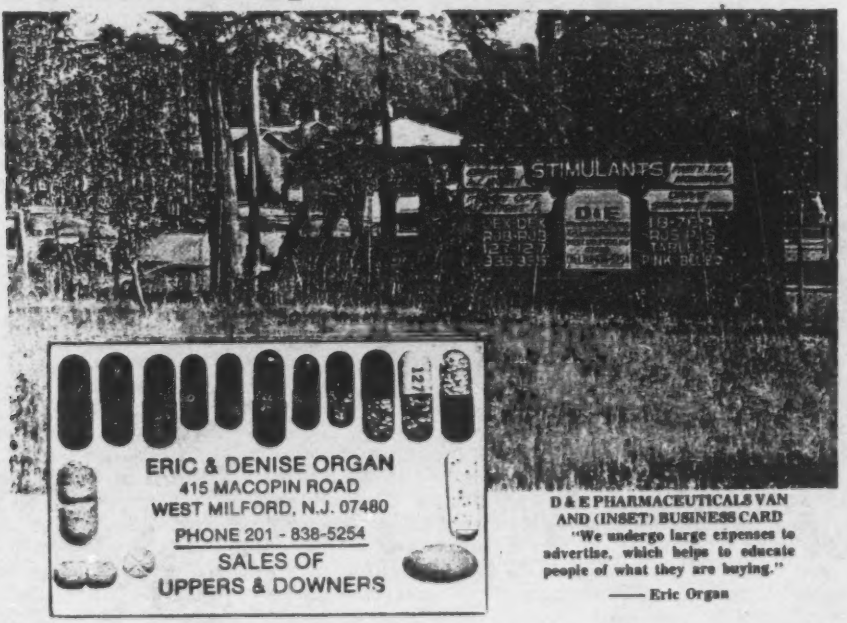
Mr. ZEFERETTI. I would appreciate that.

[The information follows:]

WM ARGUS—Sept 27, 1961

D & E Pharmaceuticals: legal, but...

Drug wholesalers arouse community concern



D & E PHARMACEUTICALS VAN AND (INSET) BUSINESS CARD

"We undergo large expenses to advertise, which helps to educate people of what they are buying."

—— Eric Organ

(By Jeff Hoyak)

WEST MILFORD.—The legal sale of non-prescription stimulant and sleep aid drugs in the First Ward, first brought to public attention by Councilman Peter Gillen 10 days ago, is rapidly stirring up community concern and alarm.

Eric and Denise Organ, owners of D & E Pharmaceuticals, a business operated out of their home at 415 Macopin Road, have a state Department Health license to wholesale non-prescription drugs. The Organs say that the thousands of pills they sell nationwide from their home contain variations of caffeine, a stimulant; phenylpropanolamine, a chemical cousin of amphetamines; and ephedrine, a vascular constrictor, and the bottles are clearly labeled with dosages and warnings. Eric Organ, 24, notes that the couple's operation passed inspection by the Federal Drug Administration as recently as June 25. Most of the Organs' business, he contends, is mail order: "Not being legally bound but by our own convictions we don't sell to anyone under 18 years of age." Organ further claims that he and his wife "are working toward stopping a black market distribution of these pills."

The operation may be legal but it's not exactly tasteful to certain segments of the community who aren't buying the Organs' public service act. Fueled by Gillen's vow to stop "fake drug" sales in his ward, the recent parking of a van garishly advertising the business (see photo) in front of the Organs' home, rumors that pills like the ones the Organs sell have found their way into the school system and the recent burst of nationwide publicity about the growing "look-alike" pill problem (including an NBC-TV news broadcast and articles in Time and People magazines), a host of community organizations last week made statements or took positions voicing their alarm and concern over the alleged sale of look-alike drugs in West Milford.

THE WORST CRIMINAL CAN BE LICENSED

Meanwhile, the state Department of Health (DOH) is "concerned" and the Passaic County Prosecutor's Office is "frustrated" over the legal loophole in the state statute which enables, in the words of First Assistant County Prosecutor John Goceljak, "The worst criminal in the world" to go down to the DOH in Trenton, plunk down $100, and get a license to wholesale non-prescription drugs: "They don't make any checks."

Lucius Bowser, acting chief of the DOH Drug Control Program, says the look-alike pill problem is this: the dealers sell the caffeine pills, which are shaped to mimic amphetamines, as amphetamines. "There's a narrow line between labeling the material and a conversation with the buyer which implies something else," explains Bowser. The buyer, according to Bowser, is accustomed to taking amphetamines, and when he takes the caffeine pills and "doesn't get a jolt," he takes more, and winds up overdosing on caffeine, which can cause heart or respiratory failure. Bowser says that at least nine deaths throughout the country have been attributed to look-alike overdoses.

According to Bowser, the difficulty in prosecuting such cases is that when the look-alike drug dealers are busted for selling controlled dangerous substances, lab results indicate that the pills contain no controlled dangerous substances, and the dealers are let off the hook.

REAL BORDERLINE OPERATIONS

Bowser says such operations are "real borderline. It's legal until the point we find out how it's not legal." Several such operations currently exist in New Jersey, and the DOH, notes Bowser, "is looking into how we can control it at the state and federal level."

Ditto the Passiac County Prosecutor's Office. Goceljak recalled that an Upper Greenwood Lake couple with same $100 DOH license file suit against the Prosecutor's Office and the West Milford Police Department after both law enforcement agencies confiscated 15,000 caffeine pills found at their residence. The suit was successful and the pills had to be returned. "You can go down to Trenton tomorrow, pay the hundred bucks and you'll be a drug wholesaler," maintains Goceljak, adding that look-alike drug dealers often buy the pills from an outfit in Pennsylvania for "two cents apiece and then sell them to students for a dollar or two dollars apiece."

Eric and Denise Organ are an attractive, friendly young couple who acknowledge the existence of the aforementioned abuses and contend they are guilty of none of them. The Organs say they have been selling pills nationwide for about a year, and the business has apparently been lucrative: Eric likes to show off the 1980 Lincoln Continental he recently bought.

The bottles of pills stored in the Organs' home are clearly labeled with ingredients, dosages and warnings that persons with heart problems should not use the

drugs. The couple says they sell 1,000 pills for $10 or $20, mostly on a mail order basis, and the pills are popular: "We've sold enough pills to supply one out of every 100 people in the United States," estimates Eric. College students and the trucking industry are major consumers of the stimulants, he contends: "Due to the numerous amount of pills sold, it is my inclination that the majority of the people aren't against this operation."

I'M NOT SELLING TO SCHOOL KIDS

The Organs insist that, in Eric's words, "We have turned down sales to minors. I'm not selling through the fence to school kids." He claims that recently two youths from Butler came to his house on mopeds seeking the drugs and "I wouldn't sell to them. I asked for their IDs."

Eric Organ also stresses that he and his wife are not dealing in look-alikes. Eric claims he has gone to great expense to buy "tooling"—metal punches to shape the pills and capsules—to give to his supplier so the pills he sells won't resemble amphetamines. However, one of the Organ's business cards, obtained by the Argus clearly shows varieties of pills that look like amphetamines (see photo) and boasts "sales of uppers and downers".

Eric contends that the couple "undergo large expenses to advertise, which helps to educate people of what they are buying. . . ." However, the ads are placed in such magazines as High Times and California Green, which speak directly to the illicit drug culture (the issue of California Green shown this reporter by the Organs had a picture of marijuana leaves on the cover), and the ads this writer saw featured only pictures of the pills, the word "Stimulants" and the address of D & E. When pressed, Eric said his newer ads, which he said he didn't have examples of "clearly indicate the ingredients of the pills, which helps to educate. . . ."

Denise Organ, 23, says the couple also advertises in college newspapers, and she had examples on hand. "That's kind of strange," feels Lucius Bowser, "since their wholesale license prohibits them from selling to someone who is the ultimate user of the drugs. They're supposed to sell to retailers and cannot engage in sales to ultimate users under the same corporate name." Bowser could not fathom how retailers would be reading college newspapers but he concedes that his agency "has no control over advertising. That may be under Consumer Affairs."

The Organs are irked by Gillen's public statement at the Sept. 10, council meeting. Without mentioning the specific name or location of the business, Gillen vowed to stop the sale of "fake drugs" in his ward "even if I have to do it myself."

Eric Organ wonders, "Why isn't our township police and Mr. Gillen somewhat happier to find . . . harmless drugs, rather than our children taking LSD or other harmful substances? . . . The trucking industry is a large part of our customers, who have for many, many years been using No-Doz, a similar drug. People also use them for dieting purposes. Why isn't Mr. Gillen disputing ShopRite or A & P for selling Dexatrim or No-Doz? . . . If the law doesn't back Mr. Gillen, to what degree will Mr. Gillen go to stop our business? Is this some sort of death threat? Or does Mr. Gillen always use such threats against people or businesses he doesn't understand or agree with and why is Mr. Gillen attempting to deceive the people with his remarks when he has never visited our establishment and never returns our calls to visit our establishment? It's comforting to know he's our councilman."

Eric Organ also claims he is being "harassed" by the township, whose zoning administrator earlier this week slapped the Organs with a warning to remove within five days the truck bearing the advertisement, which is parked in a residential zone in violation of WM ordinances, or else face a summons.

The Organ's business also complies with WM's zoning ordinance in that less than 450 square feet of space in their home is consumed by the operation.

ONE OF MY BIG THINGS IS TO BE LIKED

Eric Organ insists that he doesn't want to cause any problems: "One of my big things in life is to be liked."

In the wake of Gillen's statement, the West Milford Council of PTAs, the West Milford Business Association and the newly formed Youth and Family Counseling Advisory Committee all came out with statements in opposition to the alleged sale of look-alike drugs in town.

West Milford High School Principal Robert Gilmartin said of the D & E operation, "We're aware of it. We don't like it. It presents a potential detriment to the school environment and is an attractive nuisance. That's our obvious concern."

UNWELCOME BUSINESS

The Youth and Family Counseling Advisory Committee on Wednesday passed a resolution stating that it is "alarmed by the alleged sale of look-alike drugs in our community and surrounding areas." Rev. Frank Fowler, a Committee member speaking for himself, said that "If there are local persons selling look-alike drugs, even if they are currently within the law, it is my assumption and strong hope that all local responsibile adults and leaders will take the actions necessary to stop this unwelcome business."

Midge Touw, president of the West Milford Council of PTA, reported that the Council's Executive Board is not meeting until this week, but this is the first item on the agenda, and I'm positive the Council will take a stand against the operation, as we were instrumental in presenting an ordinance on drug paraphernalia in the town."

Paul Lampe, president of the West Milford Business Association, said the WMBA has also not yet taken an official position on the matter, but the majority of its members are "Up in arms. I don't see how they can legally sell the stuff. There's something wrong with the system. Something should be done about it."

What is being done about it is proposed federal legislation to stop it. Rep. William Hughes (D–2) of New Jersey is sponsoring a bill which would prohibit the sales of look-alike drugs. The Youth and Family Counseling Advisory Committee supports Hughes' efforts and is urging community leaders to do the same.

Meanwhile, Midge Touw is working on state legislation. Twelve states have laws barring look-alike pill sales and New Jersey is not among them. Says Touw: "Hopefully, we can get our legislators involved."

These people seem to be following John Goceljak's train of thought. In Goceljak's words, "The only answer is in legislation."

[The reply of D & E Pharmaceuticals to the preceding article, which was printed in the West Milford Argus, is inserted in the record at this point.]

[To the Editor]

THE REAL STIMULANT STORY

(By Eric Organ, President, D & E Pharmaceuticals)

ABOUT D & E PHARMACEUTICALS

D & E Pharmaceuticals does not sell any dangerous drugs. We have, however, been victimized by recent publicity attacks which have led some people to believe otherwise. The New Jersey State Department of Health, Consumer Health Service Food and Drug Division has recently approved our establishment, products, and our labeling and handling of the stimulants and sleep aids we market. D & E Pharmaceuticals will continue to provide safe, effective, over-the-counter drugs at a reasonable price.

One of the two types of products we market are sleep aids. It may surprise you to know that in a national survey of 30,000 people, it was concluded that the major consumer of these drugs are housewives and persons over 50 years of age. These customers find our sleep aids beneficial in obtaining rest and treating hypertension.

Our other product line consists of stimulants with chemical compositions closely resembling those found in the common household products No Doz and Vivarin. Our capsules and tablets can help to partially restore sensory perceptions and reflex actions which have been diminished by fatigue. They also have been proven to promote a more rapid and clearer flow of thought.

ABOUT SAFETY

Our stimulants promote safety by reducing drowsiness and helping occasional users to remain alert and attentive when working long hours. The active ingredient in all our stimulants is caffeine which is one of the oldest and least dangerous drugs known. Yes, there is a dosage of caffeine which can be fatal to man; it is estimated at 10,000 milligrams. Since tablets like our popular white crosses contain 25 milligrams, one would have to consume approximately 400 of these to obtain a lethal dose of caffeine. One could similarly overdose by consuming six gallons of strong coffee.

If one does heed the medical warnings and dosage instructions which can be found on every container we distribute, there is virtually no inherent danger in

consuming our products. Problems could possibly arise when disturbed individuals deliberately disregard dosage instructions or mix our products with other drugs or alcohol in total ignorance of the warnings. Obviously, the problem lies with the individual and not with the products he abuses.

By the tone of articles recently printed in this and other newspapers, one gets the impression that local authorities are attempting to stop our small, legitimate, business from operating. There has been no mention, however, of stopping the sales of almost identical products sold in local supermarkets and drug stores; these stores sell the products to anyone of any age at up to double the prices that D & E charges. Perhaps local authorities would consider taking the issue a bit further yet and attempt to arbitrarily impose a ban on sales of Maxwell House for being a potentially dangerous substance.

ABOUT OUR POLICIES

D & E Pharmaceuticals refuses to sell to anyone under 18 years of age. We sell wholesale only in bottles of 1,000 or more and offer the most competitive prices anywhere.

Mr. ZEFERETTI. We talked a little bit about your recommendations on the State level for laws that could be an effective instrument.

Is there anything you want to recommend to us, the Federal Government, that you feel we could put together legislatively that could have a meaningful impact on this situation. If you don't have it now, whatever way that you feel in the future we could be of assistance I hope you will contact us. This is one of the things we talked about earlier, trying to get meaningful Federal legislation.

I am a believer if you put heads together, industries together, and special interest groups together, you can formulate the tools and the kind of legislation that could be meaningful. Everybody that has a role and a responsibility should have a voice in that kind of coalition, and only that way can we find the little nuances that could be maybe effective in combating this kind of a problem.

I am going to recommend to them that your offices at least be made aware of the kinds of meetings that we are going to have, and that you should have a representative there to see if there is a way that we can formulate a kind of a strategy among yourselves that could maybe have an impact.

We don't have the dollars, the manpower, but maybe we can formulate some ideas that would have an impact.

Only by our coming here and bringing you all together and sharing can a formulation take place. Sometimes people say to us, "Why do you go into a community; why don't you stay in Washington and bring them all to you?" But we have a better flavor and a better sense of what is going on when we get to speak to gentlemen like you and other community leaders.

If there is anything you could think of today or in the future I would hope you would keep pace with us and have the kindness to write to us.

Mr. RUVOLDT. I would again emphasize, Mr. Chairman, Federal law requires a pack of cigarettes to carry the warning, "This May Be Dangerous To Your Health."

Federal law requires food to be clear as to their labels, and yet large volumes of drugs appearing to be one thing can be sold with no label whatever, no appearance as to what it contains. And that substance cannot only be dangerous in and of itself but purport to be something even more dangerous.

Certainly, since the mail is used, since the telephone, interstate commerce is used, it would appear clearly that the Federal Government could at least make it a crime, prosecutable in the Federal courts, to wholesale, distribute and manufacture, especially since the logos reproduced on these items appear to be deliberately to be what they are not, and I really think that the whole area of Federal participation against unlabeled described substances, well, I have no doubt that the business of this type of activity would diminish very rapidly if there were a requirement that they bear a label that this is a sugar pill.

Mr. FALCONE. No matter what we do at the State level, unless something is done at the Federal level, our efforts will be that much more frustrated.

Mr. ZEFERETTI. Mr. Guarini?

Mr. GUARINI. I do want to thank my good friends, Mr. Ruvoldt and Mr. Falcone, for the leadership that they have taken locally, and thank you for the benefit of your experience this morning, local and Federal officials all working together as a team.

What is most significant, is that, often the solutions for the problems and the visibility of the problems are found at the local level where you have to deal directly with the people, while Washington is so far removed.

Washington is often described as 10 square miles of Fantasy Island surrounded by reality, and it is good to have your input.

Right now I understand the Attorneys General of the States are meeting in Chicago concerning this particular problem. We do have 13 States that have model laws that follow the Delaware Act, and certainly New Jersey, which is right between the two large producers, Pennsylvania and New York, the distributors of these drugs, are really caught between a rock and a hard place. Our people are subject to this heavy market distribution of look-alike drugs, and all they can do is be a deterrent and deleterious to the health of our young people.

We start off with truck drivers, and while there is a market for them, it turned out to be a tremendous street market. As you said, what might cost the manufacture 5 cents could eventually be sold for $4 or $5, and that kind of abuse to the health of our people is unjustifiable, and I would like to see the urging of our Governor, our legislature, to put a model law into effect.

We can certainly destroy a market which is growing and has a tremendous profit and is a ripoff of the general public.

Mr. ZEFERETTI. I would like to call two gentlemen who volunteered to testify, Mr. Eric Organ and Mr. Todd Weller.

TESTIMONY OF ERIC ORGAN AND TODD WELLER, D. & E. PHARMACEUTICALS CO.

Mr. WELLER. My name is Todd Weller, and this is Eric Organ.

We are here voluntarily, hoping that maybe we can add an increased dimension to the stimulant issue based from the distributor's standpoint.

The problem associated with the stimulants are not the problems with the drugs themselves. They are caffeine, the oldest dangerous drug known to man.

There can conceivably be no law to ban sales of caffeine in any form. However, we do agree with the panel and we agree with just about everything as far as making look-alikes being illegal.

For example, biphetamines, "Black Beauties" and the "Yellow Jackets," are not available to anyone. That action is just exactly what the people in this State would like to see.

The reason they are not available is because pharmaceutical companies have come down on them. The yellow ones are Ionamins manufactured by a company called Strasenburgh.

The black ones represent 18–789 biphetamines, manufactured by Pennwalt. There are laws regarding trademarks which prevent companies from imitating their products.

The FTC has said they are free to have their own product. Well, it should be up to the pharmaceutical companies to exert pressure on those who are imitating their products.

Other than that and the prepared statement, I will be pleased to answer your questions.

[The prepared statement of Mr. Weller and Mr. Organ follows:]

PREPARED STATEMENT OF ERIC ORGAN AND TODD WELLER

ABOUT LOOK-ALIKE DRUGS

The problems associated with look-alikes are not problems inherent with the drugs themselves. It is factors which have developed around the use of these drugs which is the cause of recent alarm. A black market situation has arisen due to the public's imperfect information as to the availability of stimulants and sleep aids. Virtually all problems associated with look-alike drugs are due to improper handling, packaging, and labelling techniques. These problems are compounded by the failure of subsequent handlers of the look-alikes to properly present dosage instructions, ingredients, and complete medical warnings to the consumer.

A real danger according to the Paterson Evening News (Sept. 30, 1981) arises when "someone who has ingested the legal stimulants comes unknowingly upon the real thing." We assert that the logical solution to this is not to legislate stimulants sold as look-alikes, but to tighten restrictions on the Pharmaceutical and Drug Retailing industries, thereby keeping the dangerous drugs off of the street.

ABOUT PROPOSED LEGISLATION AND ITS EFFECTS

After examining the issue, it becomes apparent that legislation banning the sale of look-alike drugs is not only unnecessary, it is practically useless. Pharmaceutical companies themselves are best able to eliminate these imitators by using their trademark protections to force companies who produce look-alikes of their products to stop.

For example, Black Beauties and Yellow Jackets, Nos. 18–789 and RJ8 respectively, were two of the most popular look-alikes ever sold; the former look-alikes closely resemble Biphetamine, a prescription medication developed and sold by Pennwalt Corp., while the latter capsules were almost identical to Ionamins by Strasenburgh.

In just a matter of weeks, these look-alikes disappeared from the market—not available for distributors anywhere. Those who relied heavily on these particular look-alikes were out of business. This could only be initiated by pharmaceutical companies expressing their rights not to have their products imitated. No ambiguous legislation could possibly have the same effect.

D & E Pharmaceuticals will not be detrimentally affected by a law banning look-alike drugs. In fact, we expect our sales of stimulants and sleep aids to increase if a law banning look-alike drugs is passed. Even though the chemical composition of our products are identical to those being banned, ours cannot be regarded as look-alike drugs because they don't resemble or imitate any prescription drugs. Some of our products are as homogenous to D & E Pharmaceutical as No Doz is to Bristol Myers. Is a law which bans certain product forms and thereby promotes the same product in a slightly different form, any law at all?

Mr. ZEFERETTI. Make yourself comfortable.

Mr. WELLER. Is there anything we can answer for you?

Mr. ZEFERETTI. We will ask you questions but first we would like to give you the opportunity to speak first and present your side of the story.

Mr. GUARINI. Take the mike.

Mr. ORGAN. That was our statement. If there are any further questions, that sums up most of what we have to say about the look-alikes.

Mr. WELLER. If there is a law banning look-alike drugs, and apparently there is increased pressure to have one on that, ourselves as a stimulant distributor, we would really not be adversely affected.

Our sales of stimulants and sleep aids will actually increase, because we market products that are homogeneous to D. & E. Pharmaceuticals, and they are virtually the same as No Doz. The ingredients are exactly the same.

The products are homogeneous to us. They are our products. The sales will skyrocket because the demand is going to stay the same.

Mr. ZEFERETTI. How long have you been in business?

Mr. WELLER. One year.

Mr. ZEFERETTI. How did you come to be in this business? How was the business formulated? Are you both chemists, graduate chemists?

Mr. ORGAN. We have no background. I have been affiliated with the FDA through manufacturing and bottling of U.S. oxygen products, medical products, which is under the same jurisdictions that these laws pertain to.

Mr. ZEFERETTI. What kind of formal education have you had?

Mr. ORGAN. Five years experience with USP Products.

Mr. ZEFERETTI. And you?

Mr. WELLER. I am a marketing coordinator with Eric. There is no requirement as far as any specialty——

Mr. ZEFERETTI. Who produces the pills?

Mr. WELLER. USP Products and Pharmadose are two. Pressure for the large manufacturers directly on them can eliminate any pill on that table or any other pill directly.

It has been done. Half of those pills are no longer available on the market as of this day from a distributor's standpoint.

Mr. ZEFERETTI. Is this your advertisement?

Mr. WELLER. It was at one time.

Mr. ZEFERETTI. Do you advertise uppers and downers?

Mr. WELLER. No; we do not.

Mr. ZEFERETTI. How long has that been that you have not used it?

Mr. WELLER. Nine months, only by our own conscience and the public dissent against this. We realize that there will be a law passed banning look-alike drugs. We have therefore changed our whole marketing strategy to promote our own products.

Mr. ZEFERETTI. Where is your salesman working?

Mr. WELLER. Mail orders 90 percent.

Mr. ZEFERETTI. How do you know to whom you are marketing?

Mr. WELLER. We don't know in all cases.

Mr. ZEFERETTI. You made a statement that you don't sell to anybody under 18 years of age?

Mr. WELLER. That is true.

Mr. ZEFERETTI. How would you know that if your sales are 90-percent mail order?

Mr. WELLER. From the form.

Mr. ZEFERETTI. You know that there are an awful lot of young people that would not tell you how old they are if they are involved in anything like that. Anybody could sign a piece of paper and say, "I am Joe Blow and I am 21 years old." That does not mean that they are that person.

How do you verify the person with whom you are dealing?

Mr. WELLER. That is a problem inherent in that system. Minors are not legally allowed to form contracts. The fact that they do anyway is of no value to us.

Mr. ZEFERETTI. You have been in operation 1 year; how much has your business grown in that 1 year?

Mr. ORGAN. Conservatively, I am happy with our achievements.

Mr. ZEFERETTI. I am not asking you how much money you are making.

Has your business grown in 1 year?

Mr. ORGAN. Well over doubled.

Mr. ZEFERETTI. How do you advertise? How do people know how to buy from you?

Mr. ORGAN. I also advertise mostly by mail orders. I do it in school papers, magazines.

Mr. ZEFERETTI. All over the country?

Mr. ORGAN. Yes.

Mr. ZEFERETTI. You get into the school papers all over the country?

Mr. WELLER. We have been in Rutgers University.

Mr. ZEFERETTI. What does your advertisement look like?

Mr. WELLER. Our advertisement for the new D. & E., well, which helps you study. Our ads do not resemble anything made by any drug manufacturer.

Sales have been at least double due directly because the look-alikes are no longer available.

Mr. CARPENTIER. You acknowledge, though, that you started in your business through the look-alikes. Therefore, were you not exploiting the nonmedical recreational uses of those legitimate drugs?

Do you acknowledge that since you now have gotten away from this, that this is the way you did start?

Mr. WELLER. I acknowledge we did start that way. It is a profit motive, supply and demand in the market economy that required such things.

Mr. CARPENTIER. Now, you are going to go into what you feel, did you feel that that was not legitimate?

Mr. ORGAN. Based on the type of advertisement that we do do, I feel the imitation of look-alikes is not at all necessary.

I personally advertise in different areas. I advertise in a manner that exploits the looks, the numbers of printings of the particular capsules and pills.

Therefore, it allows people to see they can't be a controlled dangerous substance. It is another view of even that card there. I don't use it any longer. We are now going to be marketing three

products, but by the card's appearance, it entices people, tells them that, if I can be as outspoken to advertise, according to that——

Mr. WELLER. People realize they are not illegal.

Mr. CARPENTIER. You are exploiting the nonmedical.

Mr. WELLER. Were.

Mr. ZEFERETTI. They were exploiting?

Mr. CARPENTIER. Now you are saying, is your product, would you say it has a medical benefit?

Mr. WELLER. Oh, sure; there is no doubt about that. If one heeds the medical warnings, there is virtually no problem to be found with a stimulant and caffeine use.

Mr. ORGAN. People have been using it for years.

Mr. CARPENTIER. You feel that that is a legitimate high?

Mr. WELLER. It is not a high.

Mr. ZEFERETTI. You said you advertised in school newspapers. How does that fit in with your wholesale business, since you made a statement that you sell only wholesale and bottles of 1,000 or more, and yet you advertise in high school and college newspapers?

How does that fit in with the whole wholesale business?

Mr. WELLER. We are looking for retailers.

Mr. ZEFERETTI. You are looking for salesmen within the campus to sell your goods?

Mr. WELLER. Yes; we are.

Mr. ZEFERETTI. When they respond to you how do they respond to you, "We want to be your salesman?"

Mr. WELLER. We haven't had time to evaluate the sales to school newspapers right now. They are refusing our ads.

Mr. ZEFERETTI. You said 90 percent of your advertising is through the mail?

Mr. WELLER. No.

Mr. ORGAN. Ninety percent of our business is done through advertising.

Mr. ZEFERETTI. How much is done through schools?

Mr. ORGAN. This is a very new process we have started. To give you a complete evaluation would be difficult at this time.

Mr. ZEFERETTI. How do you draw up guidelines for distribution in schools?

How do you know with whom you are dealing?

How do you find out whether or not those people are under 18 years of age?

How do you find out just exactly what they are doing in telling people what those drugs are?

How do you know what is going on if you are doing everything through that mail process?

Do you set up a board or an office so that you could come and interview the people that are going to sell your wares?

Do you have any kind of jurisdiction over what they are saying or telling people?

Do you have any kind of representative within the confines of that particular area or State that looks at the laws in that State to see if you are violating any laws?

How do you set up an agency, by just using mail orders and gathering in the profits without knowing anything else? You are not doing anything to benefit anybody other than yourselves. You

are not finding out whether or not you are selling a type of product which could be detrimental to people, and more importantly could cause somebody's death.

I am saying to you, I don't know what kind of organization you are operating, but it seems to me you are operating the kind of organization that is not in the best interests of people and that it is purely a profitmaking business.

Mr. ORGAN. The profits have to come from somewhere.

Mr. ZEFERETTI. You don't care where the profits come from or how the profits are gathered together?

Mr. ORGAN. I do.

Mr. WELLER. We are here voluntarily, and I hope we could add some increased perspective into the stimulant business.

No, we do not necessarily follow through with our customers and find out how they are distributing them.

That is not our problem but theirs?

Mr. ZEFERETTI. It is your problem because you have the responsibility to know whether or not you are violating any law within that particular jurisdiction.

It is a problem of yours to find out whether that salesman is capable to go out and make some kind of evaluation before the selling of a substance to people.

It is your responsibility. You are a distributor of a substance.

Whether it is a controlled one, it is a substance. It is your responsibility to find out how that substance is distributed, where it is going to, to whom it is going, and whether or not there are any violations as a result of that distribution.

That is your responsibility, sir, if you are in this business, whether to do good or to make money. I understand you are in it to make money, but you are supposed to be in it also not to do anything to impact on a drug problem that we have in this Nation.

Mr. WELLER. There has been no negligence on our part and we have had no formal complaints filed against us, and so far I think we are doing a very good job to maintain all our products in complete compliance with all rules currently in force.

Mr. ZEFERETTI. One of the problems is we don't have the law on our side that maybe could make that kind of a distinction between your kind of operation and those that are legitimate operations. I think maybe that is what this hearing is all about—for us to find out if in fact we can put something together to curtail the kinds of operations such as yours. Sir, I am appalled by what I see and by what I am reading, and I am appalled by some of your answers, because you don't have a corporation structure that is meaningful or that has the answers to some of these overall problems.

I defer to Mr. Guarini.

Mr. GUARINI. I want to commend you for being courageous and forthright in coming here. Such statements as yours are of great public help and concern, and in our country we are all motivated by the profit motive and we appreciate that.

What the chairman has pointed out, that while there is a desire to obtain as good a profit as possible, we still have a public consciousness and responsibility as a distributor. As a corporation dealing with health items that affect the overall health and wel-

fare of the public, you have a very serious responsibility you carry, what people are ingesting, or taking into their systems.

I am curious to know what kind of insurance your corporation has to cover any possible injuries that might occur from the use of the products that you sell?

Mr. WELLER. The manufacturers are the people who are responsible for insuring the products. We simply distribute them.

Mr. GUARINI. You as a corporation, D. & E., have no liability insurance at all for any injuries that might be incurred to any member of the public; is that a fair statement?

Mr. ORGAN. Yes; it is.

Mr. GUARINI. Do you know whether you are selling this substance to people with heart disease or high blood pressure, diabetes, or whether or not you are actually selling a dangerous product to these people?

Mr. ORGAN. In any prescriptions over-the-counter drug it is up to the consumer to see that he can obtain those products. It clearly does state on all bottles the warnings for heart disease and obviously if someone does have a heart disease they would be more interested than anyone concerning what they should consume and what they should not.

Mr. ZEFERETTI. Well, now, your pills that carry caffeine have in it much more caffeine than a cup of coffee or what one would take in with their food and the heavy dosage levels.

Do you know what the effects are of taking excessive amounts of caffeine?

Mr. WELLER. Yes; I do. There is an estimated dose of caffeine, 10,000 milligrams. Tablets like our popular White Frost, 25 milligrams of caffeine, so it would take approximately 400 of those tablets to overdose on caffeine.

There is more caffeine in one 8-ounce cup of coffee and one could consume 6 gallons of strong coffee and die in a similar manner.

Some of our pills are much weaker than a cup of coffee. Some are equivalent to a cup of coffee. Very few are over a cup of coffee.

Mr. GUARINI. At heavier dosage levels, the effects are intensified with restlessness, anxiety, insomnia, and often produce unwelcome side effects. Is that a fair statement?

Mr. WELLER. Yes.

Mr. GUARINI. What else do you put in besides caffeine?

Mr. ORGAN. The PPA.

Mr. GUARINI. That is the phenylpropanolamine?

Mr. ORGAN. Right.

Mr. GUARINI. Do you know what the side effects of PPA are?

Mr. ORGAN. Not exactly, sir; no.

Mr. GUARINI. Let me suggest to you that PPA can trigger sudden and extreme increases in blood pressure which can be severe enough to cause the brain to rupture, and can be fatal.

It can cause a number of other adverse reactions, including dizziness, headaches, tremors, palpitations, nausea, moderate to severe anxieties, and is reported to have been responsible for many deaths.

Mr. WELLER. Perhaps the FDA should classify it as a prescription drug.

Mr. GUARINI. Would you recommend they do that?

Mr. WELLER. I would certainly recommend that they do that.

Mr. GUARINI. So you would recommend that this be a controlled drug based upon your experience in the field?

Mr. WELLER. I am not a medical person; I could not answer that, no. But if the medical society does feel that it is warranted to be a dangerous drug and one that should be required to be by prescription, I would go along with that.

Mr. GUARINI. What other substance do you put into your drugs?

Mr. WELLER. Ephedrine sulphate.

Mr. GUARINI. What does that do?

Mr. ORGAN. It is virtually a stimulant as well as a bronchial decongestant used under a certain milligram, 50 milligrams per capsule. Over that it does have different classifications and a lot of different side effects.

Mr. GUARINI. And they have the same effects as caffeine and PPA causing stimulation of the central nervous system, increased blood pressure and heart rate, constriction of the arterioles, dilation of the pupils, causing nausea, headaches, and other symptoms that can be linked with death?

Mr. ORGAN. There are side effects. I mean every drug, if we were to read prescription drugs, whatever, they would halfway scare us. These statistics that you picked from there or the rulings on it, I myself, yes, I would have to investigate it.

Mr. WELLER. We didn't come here prepared to defend the merits of each individual stimulant.

Mr. GUARINI. Do you have a chemist that works with you in your company or on your payroll?

Mr. ORGAN. Sir, the way that this works, I rely strictly on the manufacturer, as well as I do, as you can see, affiliate and educate myself in a manner a little bit more, but the manufacturer does and is responsible for the bottling——

Mr. WELLER. The purity.

Mr. GUARINI. Neither of you is a chemist?

Mr. WELLER. No; we do not need one to take a sealed bottle and merely distribute it. Where the manufacturing is done, there are chemists on the plant. It is totally controlled.

Mr. GUARINI. Have any tests been made to your knowledge as to the effect of the combination of these three drugs interacting with each other?

Mr. WELLER. Yes; there are many, many things that have been written on stimulants.

Mr. GUARINI. I realize that, but you see, sometimes there is a geometric effect instead of an arithmetic effect that takes place when you let drugs interact with each other.

Your corporation does absolutely no research whatsoever; is that correct?

Mr. WELLER. That is correct.

Mr. GUARINI. Therefore, you have no way of knowing, not being chemists, what the effect is when mixing these three drugs and interacting with each other?

Mr. WELLER. Sir, we are not involved in that.

Mr. GUARINI. If you knew that this would cause health hazards, death, injuries to people who subscribe to your drug, would you discontinue manufacturing them?

Mr. WELLER. Yes; we would. We don't manufacture.

Mr. GUARINI. You would disband your company if you knew that was to the detriment of the public health?

Mr. WELLER. I would rather not commit myself at this time.

Mr. GUARINI. You mean that you would not answer in the affirmative when I tell you that what you are doing would be contrary to the best interests of the public? You carry no insurance, so you could cause an injury or a death and not pay for the medical bills for the difficulties and troubles that you cause?

Mr. WELLER. The manufacturer should be totally responsible for the product he manufactures, not the distributor, as in the case of any distributor.

Mr. GUARINI. If you would consult a lawyer, a lawyer would tell you that you would be acting illegally.

Mr. WELLER. If we are acting illegally, why are we still in business?

Mr. GUARINI. You may not be after our hearings are over, sir.

Mr. ZEFERETTI. Before you leave, you say you are not advertising with this kind of a card any more. Do you have a new advertisement with you?

Mr. WELLER. No; but we will be willing to provide you with one in the near future.

Mr. ZEFERETTI. I would ask you to provide that and copies of what you are sending out to those newspapers in those schools.

Mr. WELLER. You can find out from us.

Mr. GUARINI. Do you have an association of other people, similar to the proprietary association you deal with, joined as members of your industry, so to speak?

Mr. WELLER. No, sir; we do not. We are a very small organization. We came here merely, although they requested many other distributors to come here as well, we came to provide you with a little information.

Mr. GUARINI. You have been very helpful.

Mr. WELLER. Well, I know you are hostile to us, naturally.

Mr. GUARINI. I think you mean well. What you don't comprehend perhaps is the gravity of what you are involved in and what has been happening around you, but it does not mean to say you are not well intended.

Mr. WELLER. What are you talking about? Are you talking about a product very similar to No Doz, any of the diet pills that are on the market, and that is exactly what you are talking about as far as composition.

The marketing, that is a whole other segment. That is where it is so broad. I can understand the copyrights, the restrictions, you don't make them look like another. What about all the others?

Mr. GUARINI. You make sleep aids, is that correct?

Mr. WELLER. Yes, we do.

Mr. GUARINI. What actual laboratory tests have you made that would indicate that they are sleep aids?

Mr. WELLER. Very similar in composition to one of the Sominex or one of the other sleep aids that are commercially available.

Mr. GUARINI. Is yours a mission down in the basement?

Mr. WELLER. Sir, they are manufactured by large manufacturing companies. It is not a basement operation.

Mr. ORGAN. We are involved in marketing. The questions that you are asking us are making it a little bit difficult for us to answer. If I were a chemist or manufacturer, it would be a little bit easier to answer some of your questions.

Mr. GUARINI. Who actually manufactures some of your stuff, a legitimate, responsible, pharmaceutical company?

Mr. ORGAN. I would say so.

Mr. GUARINI. I would like to know the name of that company.

Mr. ORGAN. Because of the controversy, the problems at this time, I would rather not say.

Mr. ZEFERETTI. Do you package your own?

Mr. ORGAN. No; I contract out all my work.

Mr. ZEFERETTI. You contract out all your work.

Do you work out of a truck?

Mr. ORGAN. No.

Mr. ZEFERETTI. Did you ever work out of a truck?

Mr. ORGAN. No, sir.

Mr. ZEFERETTI. This is not you?

Mr. ORGAN. The truck is strictly for advertisement.

Mr. ZEFERETTI. Did you advertise "Party till morning"?

Mr. ORGAN. Yes, sir.

Mr. ZEFERETTI. Did you stop that kind of advertising?

Mr. ORGAN. No, sir; that is a recent investment, sir.

Mr. ZEFERETTI. That is a recent investment.

Where you say,"Stimulants, party till morning, drive straight through." Well, I can't even make out some of this stuff, pink and blue, and all the various——

Mr. ORGAN. I would like to make a comment with reference to that, and hopefully you can grasp part of it.

By taking and advertising the products to be as they are actually seen, OK, and putting them out there, it educates the people on that. Before this panel was talking about people buying small quantities for large amounts of money by advertising them and allowing them to see exactly what the product is——

Mr. ZEFERETTI. You are advertising getting high?

Mr. WELLER. They do not get you high, sir.

Mr. ZEFERETTI. Does the bottle say, "Take this; it is going to make you high; party all night."

When you get the pills from the manufacturer, is there any evidence there that says take this, you are going to party all night?

Mr. ORGAN. No, sir.

Mr. ZEFERETTI. You do that. You tell them you are going to party all night if you take these pills. Is that your form of education?

Mr. ORGAN. Now, wait a minute.

Mr. ZEFERETTI. Well, that is what you are saying. You are saying that you advertise to educate the people that are buying it and what you are telling them is if they buy this they can party all night.

Mr. ORGAN. I am telling you, sir, by advertising and allowing the people to see exactly what it is, when they come to purchase the product they can evaluate and see it is not amphetamines or not the actual prescription drug.

It clarifies it.

Mr. ZEFERETTI. It clarifies it very well.

It clarifies the situation that you can sell it in packages the way you want, advertising it the way you want strictly on the basis of what it does to people, and not educate people as to what kind of drug they are taking; but instead say it is a look-alike to something else. It does however, educate them that they can fly all night or get high all night or whatsoever they want to do.

Thank you very much.

Mr. GUARINI. What is the normal markup in the field of those drugs?

You buy them from a manufacturer for whatever their wholesale mass manufacturing price is.

What is the percentage of markup?

Mr. ORGAN. I work on $2 to $3 per bottle.

They are anywhere from $5 to $7 a bottle. My markup is about 25 percent graduating to 35.

Mr. GUARINI. Do you package this yourself or buy the whole package?

Mr. ORGAN. In some cases I contract out the packaging as well.

Mr. GUARINI. Are there only two of you that run the whole company?

Mr. WELLER. Yes.

Mr. GUARINI. You are the entire company; no other employees of the company?

Mr. ORGAN. Right.

Mr. GUARINI. When you deal with mail order magazines, do you have to give them a percentage of——

Mr. ORGAN. We pay a fee.

Mr. GUARINI. Do you pay for the ad or do it on a contingency?

Mr. ORGAN. Pay for the advertisement, for the ad size.

Mr. ZEFERETTI. Do you pay taxes?

Mr. WELLER. Not on the wholesale level.

Mr. ZEFERETTI. Not on the wholesale level?

Mr. WELLER. Do you mean sales taxes?

Mr. ZEFERETTI. Do you sell over the counter at all?

Mr. WELLER. No.

Mr. ZEFERETTI. Only through the mail?

Mr. WELLER. One fact that I have come across in doing some research, in a national survey of 30,000 people, they found 65 percent of consumers of the sleep aids were over 50 years of age.

I think that is really remarkable, and here everyone is complaining that they are in schools.

Mr. GUARINI. Are you concerned about the school market?

Mr. WELLER. Only in colleges, universities only.

Mr. GUARINI. Do you want to exploit it?

Mr. WELLER. Nothing else.

Mr. ZEFERETTI. I would suggest that maybe you might want to sit in the audience when we have Dr. Bowser, and I shouldn't say Dr. Bowser, but Mr. Bowser, from the New Jersey Department of Health.

Maybe they can tell you something about some of the effects that some of this stuff has. It might be educational.

Mr. WELLER. I would like to know, in any proposed legislation, where will they draw the borderline between, one, that drug that

looks like another one, similar drugs, or two drugs identical or similar in composition, but do not look anything alike?

Mr. ZEFERETTI. We may not do it that way, but we can.

We will take a brief recess.

[A brief recess was taken.]

Mr. ZEFERETTI. Please find your seats.

Mr. Lucius Bowser, please. Identify yourself for the record, and we have your statement which will be included into the record in its entirety.

You may proceed in any manner you choose.

TESTIMONY OF LUCIUS BOWSER, CHIEF, DRUG CONTROL PROGRAM, NEW JERSEY DEPARTMENT OF HEALTH

Mr. BOWSER. I am acting chief of the drug control program, New Jersey State Department of Health, and we appreciate your concern over this problem and have submitted our statement from the Department on the look-alike situation.

I think the testimony we have prepared will speak for itself.

However, I would like to make some extraneous observations on what has occurred in the State of New Jersey over the past years.

Probably to the chagrin of Congressman Guarini, back in 1960, there was no regulation on drug manufacturers in the State of New Jersey whatsoever, and it was in this particular county that certain individuals made the original counterfeiting of drugs where they took legitimate drugs, not controlled drugs at the time, but heart preparations, thyroid preparations, hypertensive drugs, putting all of the markings and colors of the legitimate manufacturers. They were made under sloppy conditions here in the city of Hoboken within this county.

As a result of a criticism of the Health Department at that time, a drug control program was established.

At that time regulations were formulated and laws passed by the legislature to require registrations of anyone engaged in the manufacturing and wholesaling of drug products, whether they be prescription drugs, over-the-counter drugs, vitamins, and other types of medications.

In the beginning and up until last year, we had a staff of 13 people, and with attrition and cutbacks, we have a program of 5 people, including myself, and I am primarily an office person.

We are aware of the problems and some of the shortcomings in some of the legislation that we have as it applies to manufacturers and wholesalers.

The previous speaker mentioned his company, the D. & E. Co., which is one of the three that we have in the State of New Jersey who are registered with our department as drug wholesalers.

We have a fourth one which we are trying to get registered at the present time.

All of these have completed a registration statement listing the officers of the corporation. Two of the three have been physically inspected, and found at the time of inspection to have all the products completely labeled by the manufacturer with the warnings, labels of the manufacturer, the chemical composition of the product, and no sign of repackaging, relabeling, placing them into brown bags or sandwich bags.

We do hear that these companies are in turn not fulfilling the obligation of the wholesaler which means selling their products to someone who in turn is going to resell them again.

They are wholesaling them or applying for registration as wholesaler, and ultimately becoming a retailer and selling to the person who wants to buy, whether it is mail order, drop-in or whatever method of distribution.

Presently the law does not provide a revocation or suspension of a registration. We can take administrative action to embargo products which are misbranded or mislabeled.

We can get seizures if it is an imminent hazard to the public. We have to go through court proceedings to do so.

There are sections in the health law that do make it a misdemeanor, and I will have to clarify that I have been away, so I do not know what the new terminology is under the new criminal justice system in New Jersey.

They are probably reclassified as crimes of different degrees, and I am not familiar with what they are currently.

There is a counterfeit drug law on the books of the State of New Jersey which makes it a misdemeanor if the drugs are drugs in general, or a high misdemeanor if they are drugs that are controlled.

To the best of my knowledge, I don't know of any case to the present that has been tried under any of these statutes.

As the testimony that was presented, it would seem to criticize the health department for not doing record checks on potential registrants, whether they be manufacturers or wholesalers, or even our controlled drug manufacturers. It is a registration which merely indicates they are engaged in that type activity.

We have no provisions to conduct a background check or do a prior inspection.

We must by interpretation of the attorney general issue registrations for those people who file and have occasion to say that they are in the drug business.

Thank you.

Mr. ZEFERETTI. Thank you.

[The prepared statement of Lucius Bowser follows:]

PREPARED STATEMENT OF LUCIUS A. BOWSER

The New Jersey State Department of Health appreciates the opportunity of discussing the problems of look-alikes and to offer a possible method to control them.

Our Drug Control Program has received numerous inquiries from local municipal officials, health officers, law enforcement agencies, concerned parents, citizens groups and the press seeking answers to what the Department is doing or planning to do with respect to this problem. Our reply has been that we have virtually no control over the entrepreneur who hawks a look-alike to unsuspecting youth under the guise of being a controlled dangerous substance.

The Department has the responsibility for registering persons or firms who engage in manufacturing or wholesaling drugs of all types, controlled drugs and non-controlled drugs. Wholesaling means the sale or transfer of drugs to other than the ultimate user. In New Jersey, we do not have, to our knowledge, any firms manufacturing caffeine; or caffeine, phenylpropanolamine and ephedrine products resembling controlled dangerous substances. We do have, however, three distributors of these products registered as wholesalers and are seeking the registration of a fourth.

All three establishments meet the State's guidelines in properly maintaining correctly labeled containers of these products. We do not know for a certainty if the

products remain properly labeled at the point of sale. We hear rumors to the contrary. Should our inspectors find products not properly labeled in a wholesale establishment, the Department is obligated by Statute to detain and embargo the products as being misbranded. To date there has been no need for an embargo.

We have recently assisted the Department of Health here in Jersey City which had embargoed a quantity of the caffeine products in a retail store because the labels failed to bear the name of the manufacturer or distributor. They were sent to the supplier (our potential fourth registrant) relabeled and reshipped.

The Department feels that its current authority for detention and embargo of misbranded drugs at the manufacturing or wholesaling level and the detention and embargo by local health departments at the retail level is adequate. It is the promotion of these products beyond the normal, customary and bonafide retail sale that we are trying to correct.

The Department abhors the promotion of look-alikes upon the youth of New Jersey and the United States under the facade of being controlled dangerous substances. It is aware of the ever increasing problems of narcotic and drug abuse, not only with Heroin, now reaching epidemic proportions, but also with licit drugs such as Cocaine, Amphetamines, Methamphetamines, Barbiturates and Tranquilizers. There is an apparent growth in pill taking within today's culture. The Department does not and cannot countenance these practices.

One of the great dangers in the look-alike problem is that unsuspecting youngsters may not feel they are getting the "high" they are led to believe they will and as a result will pop two, three or even four of the caffeine products until they receive that jolt. Sometime later, having received a true to life "upper" resembling what they had previously mistaken for the upper will also take two, three or four of these more potent Amphetamine products with dire consequences.

It is most appalling to the Department to know that there are individuals in today's society who are hoodwinking our youth and profiteering, rather successfully, at the expense of the life of the youngster. The Department has even heard that one seller of look-alikes testified that what he was doing was saving the youth from the more harmful devastating ravages of the street "hard drugs". It was better to have taken "caffeine" than amphetamine, reported this "humanitarian".

The New Jersey State Department of Health would recommend to its legislators that they amend the State's controlled Dangerous Substances Act to provide penalties for offering look-alikes as controlled dangerous substances.

The Department would also welcome innovative programs by educators to enlighten our youth to the inherent dangers of drug misuse as well as the harm from the Russian roulette effect of nameless look-alikes.

In conclusion, the Department of Health feels its recommendation to the legislature and suggested innovative programs will help alleviate the problem posed by look-alikes, but not necessarily terminate it. Only when everyone, young and old, learns to respect drugs for what they are will the problems be eliminated.

We appreciate being asked to present our views and recommendations on this important subject. Our staff is available for further assistance in meeting this challenge.

Mr. ZEFERETTI. Were you in the audience when earlier witnesses were advocating some strengthening of the laws?

Mr. BOWSER. Yes.

Mr. ZEFERETTI. Do you have any ideas how those laws could be strengthened, and give one a better access to knowing who these registrants are?

Mr. BOWSER. I would, as an individual. I would not without having discussed that aspect of it with my superiors, I represent the drug program four levels down from the Commissioner. When I first spoke to her, I would say we on the program level would like to see some tightening up of that activity. We are aware that there are other surfacing drug companies whose individual officers, corporation members may have some previous involvement which may impact upon their right to conduct their legitimate business.

Mr. ZEFERETTI. What concerns me, and it frightens me also since the testimony of the two prior witnesses that all you need is $100 to get this kind of certification. There is no real investigation that

is made into the background of the individual, what they are going to establish or how the business is to be operated.

It just really boggles the mind that we could be so lenient in our procedures of giving a license to people who, in my estimation create havoc. There has to be a better way. There must be a better system that would allow you to do an effective and efficient job.

I get very disturbed when I see that people can use a truck, the back of a car, and many other modes of distributing these types of drugs and no State agency has control or authority over these operations.

It also disturbs us that it is that there is a lenient application process. There has to be another way. Your department needs to make stronger recommendations for control of these operations.

Mr. BOWSER. I am personally concerned with the situation, and I have been for many years. I have been with the Department for 19 years, beginning my 20th year this September.

As the prosecutor of Passaic County, Mr. Falcone, just mentioned, there are no limitations on who can apply, and what we must do to issue registrations.

We had over the years a firm in Jersey City who had an address on one of the local streets which was nothing but an empty store which he maintained by just paying rent on, and every time we attempted to make an inspection, there were no goods, or drugs being offered out of the premises at wholesale or otherwise, and as a result, I asked that question of our attorney general, does the registration provide that the person have a physical active operating location.

The answer came back from the attorney general, who is the top legal authority of our State, that the registration merely indicates that a person that is in that type of business does not necessarily have to have a physical location within the State.

Mr. ZEFERETTI. Do we know who these people are, their backgrounds, if they are ex-criminals, or have been in illegal narcotics operations?

Do you know anything about them other than the fact that they put down a name? Do you even know that the name is not fictitious? There has to be a better way to do this.

In New York, for example, even to be an entertainer, they take your picture, and find out something about your background.

This license is to sell a commodity, and it just lends itself to all kinds of abuses if something is not done to make an inquiry into who the applicants really are.

Mr. BOWSER. This was one of the original prefaces that the legislature looked at in 1960 when they created the food and drug laws.

There was a long discussion as to the need for licensing as contrasted to registration, and the legal determination was made that it should be a registration whereas a license would give you the right to make a prior inspection, do background checks, and there is a fine line between registration, as far as lifting it, et cetera.

Mr. ZEFERETTI. How do you make a determination as to whether the applicants are wholesalers or retailers?

How do you find out exactly what type of business they are going to operate?

Is there a follow through after the certification is issued? Or is it $100, and next year they come back with another $100 for renewal registration? Does anybody look at the company to see what type of business they are operating or is there a presumption that they are operating according to statute?

Mr. BOWSER. I issued the registration to this gentleman and the other gentleman. They found their way to Pennsylvania rather than to Trenton to apply for the registration.

I took the time to ask both the men, as well as the young lady, what they intended to sell, whom they intended to sell to, did they know the difference between wholesaling and retailing, and they led me to believe that their sales would be 100 percent to someone who was going to sell the product again.

The State of New Jersey has no control as a State agency over the retailer.

If they are going to become retail, there are registrations and licenses taken out.

Mr. ZEFERETTI. Actually determination on whether it is to be a retail on wholesale operations is by a verbal answer. If he says wholesale, it is wholesale, whether he is operating this type of business or not. Nobody really goes to find out whether or not they are wholesalers or retailers, is that correct?

Mr. BOWSER. After the fact we do make an inspection. We have inspected two out of the three that are registered. We do go to the premises to find out if the products were properly labeled, and they gave us names of people who appeared in other States who were wholesalers.

We did not see any evidence of a repackaging, relabeling or retail sale within the confines of New Jersey.

Mr. ZEFERETTI. Do they register each year, or just once?

Mr. BOWSER. It is a renewal every year.

Mr. ZEFERETTI. Is there an automatic application, and you give them the stamp of approval, or do you go out again and interview them again?

Mr. BOWSER. The renewal application is automatic, just as the initial application is automatic. If the person is in that business, we issue them a registration, and they pay their fee at the end of January.

We do have a scheduling, we are now down to four, five people in the department, and we do make inspections of a facility, and not only do we cover the over-the-counter preparation manufacturers and wholesalers, but we have 23,000 of those who handle controlled dangerous substances, the doctors, the hospitals, nursing homes, et cetera.

We try to do an inspection, annually and originally when the law became effective on the controlled substances in 1971, we tried to get to each of the 20,000-plus applicants at that time, and it has grown, at least once every 3 years.

We have not yet with the staff been able to get to all of them that we have had.

We are aware if a problem is created, or we hear of misbranding or adulteration, we have a special inspection of the premises of

these people to seize, embargo products, or if it is an imminent hazard, we go through one proceeding to court.

Mr. ZEFERETTI. Have you received any reports of deaths or injuries as a result of look-alike drugs?

Mr. BOWSER. Before we were requested to testify, several weeks ago I checked with our poison control program in our State health department who gets monthly reports from all of the hospitals in the States, plus the poison control centers, and there have not been any reported deaths from caffeine or caffeine-combination products or products that were legitimate amphetamines that were purported to be caffeine products.

Mr. ZEFERETTI. Thank you.

Mr. GUARINI. There is no way of knowing exactly how many injuries or deaths have been caused because of the reporting system not being accurate, and perhaps the doctors, are not completely aware of what kind of pills people had taken or what impact these pills had on them.

Are you saying that, as far as you are concerned, this problem does not exist in New Jersey where the health and best interests of the people are being protected?

Mr. BOWSER. Well, you have a multiple question there. How the hospitals report are not well. I would assume that there are situations that a death or an injury may be reported by some other material other than a caffeine overdose.

Mr. GUARINI. Do you feel that the Department of Health is aware of the extent of the look-alike pill industry that has developed?

Mr. BOWSER. I think there is an awareness on the part of the Department because of the number of inquiries that we have received from local health departments, police departments, and other agencies that are finding it within their jurisdiction.

Mr. GUARINI. How serious is the problem, and is it a growing problem?

Mr. BOWSER. Again hearsay situation, from those reports that we get that the police departments seem to be the ones who are getting the great brunt of the problem.

Mr. GUARINI. Does it affect our youth or the older people?

Mr. BOWSER. The promotion of the product is definitely geared to the youths of our population, school, college levels.

Mr. GUARINI. How long has our health department in the State been aware that there is a problem in getting these reports from the local police departments and that there are overdoses, or that there is a health problem?

Mr. BOWSER. The problem came to the attention of the department at the time that the previous gentleman's arrest. His arrest was in October 1980, and immediately when they found that his defense was going to be that he was a legitimate wholesaler, they came to the department and asked, did we in fact issue a registration.

Mr. GUARINI. Is that the first, and only arrest?

Mr. BOWSER. The only arrest?

Mr. GUARINI. No arrests by the State since then. Only one arrest on the books as far as look-alike drugs that your department participated in?

Mr. BOWSER. That is the only arrest that I know of. We did cooperate with the health department here of Jersey City just about 2 weeks ago.

They had a retail store that had products which were not labeled with the name of the wholesaler or manufacturer and the local health department embargoed them, and we made arrangements for the products to be shipped back to the Netcong Vitamin Co., and had them relabeled with the name of the original manufacturer.

Mr. GUARINI. Are there any legitimate pharmaceutical companies in New Jersey involved in this business or making money out of this business, directly or indirectly?

Mr. BOWSER. I would say the answer is no, if you are talking about look-alikes. We do have legitimate firms in the State of New Jersey who are making look-alikes for the general generic drugs of all types.

Mr. GUARINI. Address uncontrolled substances. There are only three companies that manufacture capsules in the United States?

Mr. BOWSER. I don't know the count. I know at one time there was only two.

Mr. GUARINI. Some of those companies are based here, Lilly or Parke-Davis, and Warner-Lambert.

Mr. BOWSER. Warner-Lambert has a facility here. Parke-Davis is a subsidiary of Lambert.

Mr. GUARINI. Has the health department made any inquiry into that company as to the sale of the capsules, that which look-alike ingredients are put into?

Mr. BOWSER. The State health department has not visited Lambert or the Parke-Davis, which is one in the same.

Mr. GUARINI. What you are telling me is that the health department really has not done anything effectively, or does it even have much data with regard to this particular problem that we are talking about today?

Mr. BOWSER. That is correct. When we did inspect products at one of the firms, they were in not look-alikes, but they were being offered as, I mean, we did not find the black beauty capsules. We found a capsule which had the caffeine, PPA, but not black.

Mr. GUARINI. You were here when the gentleman from D. & E. testified that they had absolutely no insurance on their company, and they are distributors of PPA, amphetamines and ephedrine caffeine pills, and say that they have tried to comply with the law.

How does the health department deal with this particular problem, recognizing the fact that if there is a death or injury, that there is no responsibility on the part of the distributor of the drug itself? They don't even have any concern about that insurance?

Does the health department ask any questions as to whether or not these people are responsible people dealing with the public?

Mr. BOWSER. No, the application merely lists the names of the officers and their home addresses and the physical location of the practice.

Mr. GUARINI. As an administrative agency, don't you have the right to make your registration form more complete so that you know more fully the responsibility of the people that are dealing

with these substances, and if they answer it wrong, are they liable for perjury or misstatement of fact?

Mr. BOWSER. The registration statement was mandated in the original New Jersey food and drug laws which is what we operated under.

Mr. GUARINI. Did you put together the registration statement?

Mr. BOWSER. No, we did not. The legislature made the registration statement and presented it.

Mr. GUARINI. You have no jurisdiction to ask whether or not there is financial responsibility on the part of the company that you are registering?

Mr. BOWSER. At the present time, the way the application is devised, that is not, I would not say, not of interest, but it is not part of the information we seek.

Mr. GUARINI. As a health officer for 20 years, wouldn't that be something that should be brought to the attention of the Health Department, that they should seek changes and make suggestions and recommendations to the legislature so that the people are better protected by our State laws?

Mr. BOWSER. I would say that is a valid statement.

We have not pursued that over the years.

We have tried to upgrade the food and drug laws to cover many areas, but that has not been one of them.

Mr. GUARINI. Well, 13 States in our Union have passed model codes to protect their people from the counterfeiting of drugs and look-alike drugs.

What recommendations has the Health Department of the State of New Jersey made, and specifically what has been done by the Health Department in this district, if anything?

Mr. BOWSER. The Department has made a recommendation that the State's Controlled Dangerous Substances Act should be amended. The Department did not want to go on record as recommending any dollar penalty or any length of incarceration, just that it would be amended to provide penalties for anyone making look-alikes.

We have not instituted any other changes in any of our food and drug laws or our Controlled Dangerous Substances Act.

Mr. GUARINI. Have you been working closely with the DEA, FDA, or the FTC?

Mr. BOWSER. We have a working relationship with the State FDA.

Mr. GUARINI. With regard to this particular subject matter, have you been working with the Federal and the local authorities in trying to put together an effective program?

Two prosecutors just testified that there is a very apparent problem that exists in the streets with our young people concerning the hazards to their health from these look-alikes.

Is there anything that you will recommend concerning the elimination of this kind of problem, because although the Federal Government has responsibility, we recognize the State Department also has responsibility. What are your recommendations concerning a solution to the problem that has been created in our school systems, as was pointed out by the two prosecutors.

Mr. BOWSER. The Department looks at it, and maybe I might be more speaking as from my own personal observation rather than

the policy of the Department. Our Controlled Substances Act could eliminate some of the problems if the penalties were the same, if the products being offered were a controlled substance.

I also think that the products are that closely resembling a counterfeit to the point where their color, shape, tablet design, et cetera, then we have a counterfeit drug law on the book which is a criminal section, and the Health Department is not a criminal agency.

Mr. GUARINI. Do you work with the Attorney General?

Mr. BOWSER. Yes, and we recommend that the drug laws also be applied to cosmetics and devices.

Mr. GUARINI. Have you made any recommendation for prosecution on controlled substances to date in New Jersey?

Mr. BOWSER. No, because we have not found anyone manufacturing or wholesaling these products as a counterfeit substance in the State of New Jersey.

Mr. GUARINI. Do you concede the fact that there is a problem?

Mr. BOWSER. Based on the information received, there appears to be a problem that the law enforcement people are generating.

Mr. GUARINI. Are you so understaffed in your Department that you are unable to address yourself to the problem? Is there, in fact, a financial or staffing problem in the Health Department?

Mr. BOWSER. Our staff has been reduced, and we have five people, including myself, to cover the entire State of New Jersey for not only the over-the-counter drugs, but the legitimate prescription drugs and all of the controlled substances, as well as other areas under our jurisdiction.

It is an impossibility for four people to cover an entire State adequately, to run inspections and investigations, and our drug program, I believe, has received the lowest priority in the Health Department's funding, as far as all the other activities of things.

Mr. GUARINI. It is a fair statement to say that look-alike drugs and the counterfeiting of drugs that we have been addressing ourselves to here today has been relegated a low priority in the health department of our State because of budgeting, funding, unavailability of staff, or other reasons?

Mr. BOWSER. I would say it has not been discussed to a great degree by the Department as a whole to set it up in any priority level. It is just what the drug program my own unit has been aware of is and been able to inform the Commissioner, and our Deputy Commissioners what the problem is. We have not addressed the issue of priorities.

Mr. ZEFERETTI. Mr. Bowser, I have a comment, not a question really.

It seems to me, the State legislature can enact the kind of legislation that makes it possible for you to register and certify the registration, but it would seem to me also you can regulate within that scope of law the kind of rules necessary to make that application stand out, and maybe, looking at the regulations, because you have the right to regulate your own agency to that degree, maybe you can tie in some of the kinds of questions within that registration form that could be meaningful and that could at least lend itself to know who the people are registering and create a better knowledge of who is in the distribution business really.

And I would think that maybe under the law, under the existing law, that there are ways to regulate that and tie that in, and I would ask you, sir, to please make that kind of investigation for us. And if there is, at least bring to the attention of the Commissioner and those that have jurisdiction, the kinds of concerns that we have expressed here today, and I thank you so much for your contribution.

Mr. BOWSER. I will bring back your concerns concerning the possibility of regulation, but we cannot go beyond the scope of those.

Mr. ZEFERETTI. I understand that.

Thank you so much.

Dr. Arthur Leibowitz, please.

We have your statement, and it will be made a part of the record in its entirety. You can proceed in any manner with which you feel comfortable. Would you first please identify yourself for the record.

TESTIMONY OF ARTHUR N. LEIBOWITZ, PEDIATRICIAN, PHILADELPHIA, PA.

Dr. LEIBOWITZ. My name is Arthur Leibowitz. I am a medical physician licensed in the State of Pennsylvania.

I am a Board certified pediatrician in private practice, just outside of Philadelphia, and a Fellow of the American Academy of Pediatricians. I speak for myself, however.

I have a prepared statement. I would like to go through it and talk to you.

I hope that really from this we can get a give-and-take of some of the medical aspects of this problem that have not been directly addressed this morning.

I think that part of the significance of this as a medical problem is the way that I became involved in it.

This summer while working in my office, one of our nurses reported to me the tale of a neighbor child of hers who had suffered a stroke, and we were discussing how unusual strokes were in children, and how severely involved this child was, and where she was undergoing care, and that happened to be at one of the hospitals which I am a member of the staff.

By coincidence, I caught the tail end of a radio broadcast on public radio mentioning that children who have been reported to take medications are having strokes, and I sought out the people involved in the care of this child to ask if they were aware that perhaps the child indeed had had a reaction from drugs.

At that time, they were still in the process of trying to delineate the nature of her problem, and really nothing more was said of it.

About 4 or 5 days after that time I got a phone call from one of the neurologists involved in that child's care, and he said, "What in the world are you talking about, about strokes and drugs?"

I said, "Quite honestly, I am relating something to you I am picking up on the radio."

We set about then to try to find out where all this stuff was coming from.

The significance of what I have just told you is that this problem is not a problem on the medical conscience, at least of the practicing pediatrician. With isolated examples, really nobody has any

information through the medical process the topic of look-alikes, and while I represent that as no sort of scientific study, in mentioning it to people who are responsible for 90 percent of all the care that occurs in the regions surrounding the southwestern portion of Philadelphia, in mentioning to that group of doctors through various hospital meetings, the topics of look-alikes, ephedrine, PPA, and caffeine, I was not able to find one person who gave any indication at all to the awareness that these drugs were not safe.

You could not find one of those people who in each and every day has not recommended or prescribed the use of an agent containing PPA.

They are everywhere, in literally a hundred different preparations both by prescription and nonprescription, and to be perfectly honest, until this summer I, and probably continuing now most physicians, have absolutely no idea that they are not safe.

Suffice it to go on with this story of the children involved. The police, on dropping her off at the hospital, dropped her off and said, "Oh, she is a drug overdose."

The hospital treated her for a typical overdose, a child who was lethargic and unable to give them a clear history of what she had taken.

Through the course of the proceeding the following several days, it became clear this child had a massive stroke. Only then did the toxicology reports on the preparations involved come back.

Only then did the final statement on her toxicology and her blood studies done at the time of her admission reveal that both the pills she had on her possession and the blood circulating through her body contained PPA, ephedrine, and caffeine.

The child has since this summer gone through an extended period of rehabilitation. She is now able to walk with a walk aid, a walker. She walks with a profound and severe limp. She has complete and total loss of her right arm's function, and can mumble only approximately a half dozen incoherent words.

It is not likely that she will ever retain any degree of what would be considered normal function in view of the severity of her involvement and the slow return of her improvement.

There was some question whether or not she was lucky to be alive.

The pills themselves are a problem that exist on basically two levels, and most of what we have said this morning has been emphasizing the fact that they are very legal, at least in the current definition of the law.

They are also an extremely big business.

While we were not aware of the problem, we took one of them, in this particular case, it was a black capsule, what is made to look like biphetamine that the police returned to us. We took one of them to the pediatric ward, and at the time there was a fellow who had a history of drug involvement, and we asked him if he knew what the pill was. He looked at it, and in a flash said "It is not what you think it is."

He said, "It is not an ampnetamine, it is a look-alike."

Yet the people in the hospital emergency room, when they were shown the pill, mistakenly identified it as one of the real biphetamine capsules.

You have to be very good to pick up what is going on, and be aware that it is going on at all; and as I mentioned, the medical community is not aware that it is going on.

The pills are identical in size and shape and labeled with some sort of ink marking that can be smeared if you wet it.

The numbers involved, for example, we are talking about a pill that is about a half inch in size that might have been carried in somebody's hand. A legitimate biphetamine capsule has a code mark 18-875, and a little logo that is distinctive for the Pennwalt Corp.

Look-alikes have been found to carry logos 18-845, 18-858, 18-789. You smear them up a little bit, and you can't tell what they are, so this is definitely a major aspect of the nature of the problem.

The pills are advertised as being safe, and in the aspect of advertising to a school age population, despite what these gentlemen have mentioned as far as their advertising being tailored to the college student, our problem involves the use in high school and surrounding areas.

They are advertised in media, magazines as legal stimulants, and always the word "legal" is emphasized. It is hard to convince people that these preparations when used in so many over-the-counter applications, advertised openly, sold as legal, are in fact very dangerous, and one of the aspects of control that will aid those involved in drug education will be to eliminate the word "legal", so at least the stigma of using an illegal product will be there.

I think that that will go a long way toward making the potential user aware of the danger involved, but I would prefer right now to talk to you about what I consider a more rational approach, and that would be to control the use of the agents in the over-the-counter market regardless.

As mentioned previously, caffeine is a very difficult to control subject. We all drink coffee, and coffee has in it about the same amount of caffeine as one of these capsules. It is also extremely easy to prepare. No doubt each organic chemistry freshman in college has done the experiment extracting caffeine from tea. It takes about a half hour, and you end up with pure caffeine with very little difficulty, and I firmly believe that in the mixtures we are talking about, caffeine is not the problem.

It is a stimulant, there is no question about that. However, I think that the two other agents, PPA and ephedrine are a more serious component.

I am unable to find on the market currently any legitimate over-the-counter preparation that includes all three of these chemicals. They are being sold as, they must be OK, because there are diet pills, and indeed there are pills that contain caffeine, pills that contain both PPA and caffeine, but the unique mixture is not being sold legitimately in this country at this time.

Mr. ZEFERETTI. Is there any rationale or medical purposes for the mixing of this combination?

Dr. LEIBOWITZ. Absolutely not. Mr. Guarini mentioned before using the term geometric additions, the medical term for that is synergism.

You have two agents called sympathomimetric amines.

If you have ever been walking down the street and somebody comes up behind you and startles you, you have this rush that goes through your body. Several unrecognizable things do happen to you during that time.

Those things are the side effects of these preparations. Now, the side effects to a given drug may be the desired effect of another one. In other words, ephedrine has the property of opening the airways in your lungs. It relaxes the muscle that narrows the lungs. As a side effect of that medication, it is also a blood pressure elevator. If you have a condition where your airways in your lung were narrowed, as in asthma, it might be well to take ephedrine.

In the other circumstance where you needed your blood pressure elevated, the side effect of that drug could be very desirable, and if your airways in your lungs were already open, you would have very little effect in your lung, and you may get the desired elevation in blood pressure.

That is an example of how the side effects turn into the desired effects.

This entire group of preparations includes phenylpropanolamine, ephedrine, and they are merely at two different ends of the spectrum of action of drugs.

Also included in this list of agents are the legitimate amphetamines.

Ephedrine is an agent that is practically never used in prescription medicines any longer. The basic problem is that it was designed to address was the one I mentioned, taking a person who has asthma and getting his airways to open up to relieve the congestion in his lungs.

The problem with it became, the side effects were so dramatic, most people that took enough to do that became restless, hyper, lost their ability to sleep and function to such a great degree that ephedrine lost favor in the mid-1970's.

Now, we have a whole industry dedicated to developing what are basically better ephedrine-like agents that have the property of opening the airways of the lungs without causing so much of the central nervous stimulation, increasing heart rate and blood pressure that was such a difficult side effect.

Now it is used primarly in a couple of, perhaps a half dozen different prescription cough preparations. It is used in some eyedrops, because one of its properties is to dilate the pupils of the eye and is used in over-the-counter preparations that have very little, compared to the prescription.

The other agent, phenylpropanolamine, is basically an agent change. It has almost no property on opening the airways of the lungs, but because of its properties on shrinking down the size of the blood vessels, it is used as a nasal decongestant, and has surfaced as an appetite suppressant. There is no evidence supporting that PPA has any effect on suppressing anybody's appetite. It—when you have a cold, you don't feel much like eating.

When you control, with sugar pills, in a double-blind fashion, it really does not have the properties of appetite suppression.

Mr. ZEFERETTI Are you advocating that these drugs be controlled substances?

Dr. LEIBOWITZ. We could lose ephedrine from the market and never suffer.

It could simply become a controlled substance, and indeed I believe that the amount of ephedrine available over-the-counter is controlled. It appears to me in the preparation of sulfur, without the prescription there is much less effect in the uses than it is found to be continually in the controlled prescription market. Phenylpropanolamine is a decongestant that has gained wide acceptance.

Whether or not it truly works is open to question. It has been classified as probably effective to clear a runny nose and a cold.

There are other agents available. We previously thought that phenylpropanolamine was safe, and increasing evidence of experiences indicates that in certain people, it is quite unsafe, and you can't predict which people they are.

My only hesitation is that because the agents related to phenylpropanolamine that would be used for alternatives, specifically talking about most likely a drug called pseudoephedrine, and another drug called phenylephrine, which are similarly now unrestricted. They can be bought over the counter.

I imagine that if we lost phenylpropanolamine from the over-the-counter market, it would be replaced by either pseudoephedrine or phenylephrine.

I don't know that they are safe either because nobody has looked at the issue, but nobody looked at phenylpropanolamine until approximately 5 years ago.

It would be a tragic shame to eliminate one and trade the problem for another.

Realistically, what we have to do is restrict the use of the drugs over the counter. That will increase the medical awareness that the drugs are not safe.

I hold myself up in front of this council, but I don't feel I am unique. One of the things that is a common practice when you deal in pediatrics, children of different ages, different body sizes and different weights at this particular time of handling particular medications in their body, something that is a fairly common practice is to feel that with certain particular agents, if a little bit doesn't work, a little more might, and we would, until all of this information that became available to us, a practice of saying to somebody whose child was taking one of the decongestant kinds of medicines in what seemed to be a well-tolerated, recommended safe level, that if there was room to increase it and still stay within the safe recommended level, increase it a bit.

I have severe hesitancy about what the medical community has been practicing because of ignorance. We were not aware that these drugs carry any dangers toward severe disability or even death from this use.

We have all seen kids whose mothers will call us on the phone the next day, and say, "Johnny didn't sleep last night when I gave

him the medicine." You say, "Try a different medicine," but none of us have any awareness of the profound difficulty that can occur.

Maybe the drug prescription in a more descriptive way will increase the medical awareness of the problem or the potential for problems.

Mr. ZEFERETTI. I couldn't agree with you more. I am looking for a way to have the medical profession become aware of this problem. We are now just reaching the point where the public is becoming aware of the problem. I would suggest that situation is something your own profession should have been involved in for a long time. I known it is a question of knowing what the end results are from these particular drugs. If we know that certain drugs are used unlawfully or in the wrong way, that they could be detrimental in the sense of losing life or injury, then they should be restricted.

Dr. LEIBOWITZ. The over-the-counter drug, legitimate manufacturers, they will raise issue with our assessment that the drugs are not safe.

I think that the body of evidence is accumulating to convince them of that, and they will also talk about the profound economic implications of the change.

In fact, over-the-counter medications are changed on a nearly continuous basis.

I have, in my report to you, mentioned a product produced by Mead Johnson. The Federal Drug Administration has cracked down on what are considered to be fixed preparations of dissimilar types of drugs. You can't mix any longer aspirin with decongestants and end up with something that will make your pain go away while you have a cold.

Now, they are saying you should take aspirin and a decongestant, but we don't want the manufacturer to sell you them together in one bottle.

There is a product on the market called Trind, and it was a mixture of a decongestant and an amphetamine, and because of the reformulation Mead Johnson took the antihistamine out of Trind as requested, and increased the phenylpropanolamine five times.

It is still within a safe level, but they have basically looked past one problem to another.

Certainly the pseudoephedrine doesn't belong in a cold preparation, no question about that; but when the answer is, this is still a permitted product at a permitted amount, and you trade off probably a much safer drug for one that is potentially more dangerous, I am not sure that the public has been served very well.

Mr. ZEFERETTI. I don't think any of us are really aware since advertisements on television and other media are promoting combination formulas. Many people want one pill to resolve all their problems.

We, as lay people, are enticed by somebody's advertising indicating that we can get immediate relief.

That is why I stated that your profession has to look at these drugs and combinations. Distinctions have to be drawn, and there needs to be a policing of these various kinds of drugs. The policy has to take into account what the needs of people are, and beyond that, what injury could result as someone who might abuse that particular drug?

Dr. LEIBOWITZ. We want the pill that will make our symptoms go away, and we are in a very pill- and drug-oriented society.

The problem of the look-alike is the mirror or the problem of society, not the cause of it. If we were in a society that taught us that we don't take pills to make us feel happy at night, or that we don't take medication to stay awake, we go to sleep instead, we would all be a lot better off.

It is the same pressure on the pediatrician. The same people who would sit there, and say "I don't take anything when I have a cold," they bring their little 2-year-old to our office and say, "Johnny has a runny nose. Can't you make it go away?"

There is a lot of pressure upon us to answer the need of people. It is much easier to say "Yes, go buy this" than say, "Look, it really doesn't bother him to have a runny nose. Let him go."

Mr. ZEFERETTI. There is a whole phenomenon which exists, you get more pressure, so you give a stronger drug. Everything is oriented toward that avenue, and we are becoming a society of drug users.

[The prepared statement of Arthur N. Leibowitz follows:]

PREPARED STATEMENT OF ARTHUR N. LEIBOWITZ, M.D.

CASE REPORT

This summer a 14 year old girl was brought to the Emergency Room of a hospital in Suburban Philadelphia by the police. She had been babysitting for a neighbor and when she failed to answer her mother's phone call, her mother went to investigate. She found her daughter disoriented and speaking incoherently, very lethargic and complaining of a headache. Her mother called the police and they brought her to the hospital.

Because of her state, the child could give no history, but pills were found in her purse which appeared to be amphetamines. Studies were sent to the lab. The following day the child was worse. She was increasingly disoriented, unable to speak or use the right side of her body. An arteriogram originally suggested the possibility of a brain tumor. A subsequent C.A.T. scan however showed the pattern of a classic stroke. Analysis of the patient's blood and the pills she had in her pocket showed them to contain a mixture of phenylpropanolamine, ephedrine, and caffeine.

After extensive rehabilitation this child can now speak several difficult to understand words, and walk with a severe limp. She has almost no use of her right arm. It is not known how much function will ultimately return, but judging from the severity of her involvement and the slow improvement made so far, one would not be optimistic.

It is unfortunate and tragic that pills and drugs are a fact of life for many school aged children. But the problems in dealing with "Look Alike" drugs are unique, because they are being sold openly and are advertised as being a safe stimulant that can be used to get more "Kick" out of life.

An estimate of the magnitude of the problem is impossible. Until recently no one had really paid much attention to the issue, no doubt because of the seemingly benign nature of the drugs involved. Much more is being written in the lay press and brought out by the media than has been published in the medical literature. My own involvement began when I happened to hear a radio news broadcast done last summer on Public Radio. Suffice to say that this is a multimillion dollar enterprise of which most of the medical community is unaware.

The problem exists on two levels. The first is the very idea of marketing a "Look Alike"—a pill made to look like another regulated, prescription and potentially abusable drug. The benefit of this to the buyer obviously is an enormous opportunity for profit. Illicit street drugs sell at prices many times higher than they can be purchased for legitimately. The drugs can be resold to users who believe them to be other restricted drugs at many times their original cost.

Interestingly, to date, legislation has been directed against only this aspect of these drugs. In Pennsylvania it is now illegal to sell a pill made to look like another regulated product. While this may be an expedient attempt to control these drugs, it does not address the basic problem of their use as what they are: a combination of

three drugs capable of turning a perfectly normal child into a vegetable for ever. To some they may be lethal.

Without being too technical, these pills contain about 35–50 mg. of phenylpropanolamine (PPA), 8–10 mg. of ephedrine and 200 mg. of caffeine. A cup of coffee has about 200 mg. of caffeine.

PPA and Ephedrine are both related sympathomimetic agents. They work on the nervous system's adrenergic nerves. PPA is marketed primarily as a decongestant. It is used in hundreds of preparations available both by prescription and over-the-counter. It has also recently surfaced as an appetite suppressant but it's true effectiveness in this regard is open to question.

Ephedrine is mainly used in asthma to open the airways of the lungs. In actual practice it is little used today because better agents with fewer side effects have been developed.

Both of these drugs have as modes of action effects on blood vessels, heart beat, blood pressure and stimulation of the brain. Caffeine is a stimulant also. It is not known whether it is the dose taken or some individual sensitivity which allows this combination to cause it's devastating effects. It has been reported that a teenager has had a stroke after taking only one pill, however. Unfortunately in actual practice many users take several pills at once often washing them down with an alcoholic beverage.

In a stroke, a blood vessel in the brain bursts, and the portion of the brain it supplies dies. If a major vessel breaks death can result, if a smaller vessel further along ruptures, paralysis, loss of speech, or perhaps blindness could occur.

And these drugs are sold as safe stimulants which will give more "Kick" out of life!

I believe that the legal solution to this problem should be direct. We should not focus on the "Look Alike" aspect of these products. Rather we should control their sale by restricting their ingredients. Simply reducing the amount permitted in each pill would not work, as multiple pills can be taken to make up for the difference. This would put the now legitimate producers and sellers out of business. Of course they could go underground, but this would make their sale much more difficult and less blatant. Restriction would also allow us to make clear the dangers of these pills to their potential users, something which is difficult to do when they can be bought, sold and advertised so openly.

As far as medical consequences of restriction, there would be few. Physicians could still prescribe these medications where indicated. While there may be an initial roar from the Over-the-counter Drug Industry, other, probably (possibly) safer substitutes exist. Reformulations of over-the-counter drugs are common and cause barely a ripple in sales. (As an example Trind, manufactured by Mead Johnson, has just been reformulated to include more phenylpropanolamine than previously!)

As a physician, I would also hope that more awareness of the dangers of what is probably the most commonly recommended non-aspirin like agent would be more widely recognized. Even as professionals, we too tend to believe that if a drug is sold without a prescription it must be safe. We complain constantly about drug over-regulation and resulting delays in obtaining for use the newest agents reported to be effective in foreign trials. Perhaps we should recognize that even approval for use here in this country does not insure a product's safety, and that even the most common drugs harbor the potential for terrible abuse and danger.

Mr. ZEFERETTI. Mr. Guarini.

Mr. GUARINI. Thank you for your very lucid, helpful testimony, Doctor. My understanding and observation is that the American Medical Association hasn't got into this issue. Would you suggest one of the solutions would be to restrict the mixing of these drugs, PPA and caffeine?

Dr. LEIBOWITZ. Restricting this sale in the nonprescription market is an approach, and once you do that, I believe that that is a better attitude than simply restricting their mixing in the same pill.

Similarly, reducing the amount available won't work. You don't have to be a genius to know you can buy ephedrine plain, phenylpropanolamine plain, take two pills, and you have accomplished the same thing as the look-alike.

Mr. GUARINI. Would we then have to make them a controlled substance?

Dr. LEIBOWITZ. I think they would have to go back on the prescription list. That does not insure that they will not be abused.

Mr. GUARINI. That helps to address the problem.

The geniuses of the business community will always find a way to do something else later on.

Dr. LEIBOWITZ. In addition to legitimatizing of this agent is that it is extremely cheap, and our experience is that restricted drugs sold illicitly are much more expensive than look-alikes, and part of the appeal of the look-alike is a stimulant that you can buy, if you buy it on the street for a heck of a lot less than you can buy a legitimate amphetamine capsule, and making them go underground would certainly increase the cost.

If you look at it from purely a control situation, you may not have gained all that much. You take them out of the hands of the casual, look how cheap you can get them.

Mr. GUARINI. Would you say that the ball is in the court of the Federal Drug Administration to reclassify the drug?

Dr. LEIBOWITZ. Unquestionably, that is true. When I was trying to find out where this report came from, I tried to get as much information about a subject that I could not find written up at all in the medical literature. I called the FDA and spoke to a fellow on the phone, and I mentioned look-alikes, and he didn't know what I was speaking about. He said, "You must be in the wrong department."

Phenylpropanolamine is being looked into by somebody, and so I spoke to him. They had three reports of people who took Dietab, which is a phenylpropanolamine diet aid pill sold legitimately over the counter, three reports of people who took that who had problems with their blood pressure, and he was fascinated when I told them we were looking into the possibility of a stroke, but they had no information about it. I spoke with a reporter for public radio and related that tale to him. He said, "You talked to the wrong fellow."

I became an expert on this subject because I listened to a radio show.

I got called by one of the counsel for the Senate, counsel for Senator Hughes, asking me how they could find out enough information to find some medical people to talk on the subject.

Mr. ZEFERETTI. Representative Hughes?

Dr. LEIBOWITZ. I spoke to him for a while.

He said, "You are the only person I ever spoke to in a way I could understand."

There is not a lot of medical awareness, not a lot of public awareness.

Mr. ZEFERETTI. Maybe if we continue in this avenue the way we are going, maybe we will bring that awareness to them.

Thank you, Doctor.

I would like to call Mr. James R. Zazzali.

You may proceed.

TESTIMONY OF JAMES R. ZAZZALI, ATTORNEY GENERAL, STATE OF NEW JERSEY, ACCOMPANIED BY JAMES F. MULVIHILL, ASSISTANT ATTORNEY GENERAL, CHIEF, PROSECUTORS SUPERVISORY SECTION, AND J. FAHY, DEPUTY ATTORNEY GENERAL

Mr. ZAZZALI. With me are James Mulvihill who is the Chief of the Prosecutors Supervisory Section, and Deputy Attorney General Jack Fahy, who is familiar with the issue.

I will be brief today.

I know you have many witnesses, and I will summarize my statement.

I thank you, and a couple of remarks have just been made. We need to increase public awareness of this issue.

It is significant that I find a certain "so what" attitude on the part of all too many people, both in and outside of law enforcement.

They view the problem erroneously as an innocuous problem. It clearly is not that.

I would ask you at the risk of sounding simplistic, in order to show our perspective of the problem, we considered two possibilities, an A list and a B list.

Look at aspirin, caffeine, ephedrine, and PPA under the A list.

Look at marihuana, barbiturates, amphetamines, and heroin under column B.

The difference is the A list is not regulated.

What disturbs me, at the risk of sounding simplistic, are similarities between the two lists. First, the similarities between the look-alike drugs and the more serious drugs.

The similarities are quite simply that those substances, when abused, can create serious health problems.

A second, the look-alike drugs are being peddled by certain irresponsible people just like any other type of controlled, dangerous substances, but the look-alike drugs are selling for $2.50, $3 a pill, whatever, when in fact they take a couple of pennies to manufacture.

We know of the recent magazine article and other sources which portray health hazards and death.

You are all familiar with the Illinois experience where you had what, reportedly 6 deaths from improper use of those look-alike substances, 10 year old children dying of overdoses of caffeine and that type of problem.

I heard a talk about one of the A lists as I described them, one of the look-alike substances such as ephedrine and the fact that he indicated asthmatics have to use ephedrine, and they often suffer a hyper effect.

I have been an asthmatic for 35 years, and I listened to that with interest, and I am a little hyper at times, although I don't attribute it to the ephedrine, but I seriously am concerned. And I think back 20, 25 years ago. I took ephedrine for my asthma, and one or two times I went out racing to play basketball, and my physician was alarmed and angry at that.

I in turn am alarmed today now, thinking about the kid who is using ephedrine and does not have the benefit of a doctor monitoring that situation.

You may have had another Attorney General sitting here today, but for that physician helping me.

They are using it for side effects.

The horror stories that came out of England, I was reading a few, a form of ephedrine causing in that period of time, over the course of a year, 50 or 60 deaths because of improper use of a certain type of ephedrine which was not properly tested.

As to the experience in New Jersey, as to the extent of the problem here, both Mr. Mulvihill and Fahy helped me to look at the question, and we do find after contacting several prosecutors, and certain municipal police departments, large quantities of look-alike pills including the pseudo phenylpropanolamine have been in various counties.

We find that several persons have been operating very profitable businesses in the look-alike pill trade, and to my distress, and I think it is an incident, or a number of incidents which give pause, we find so many of these people using flyers and brochures to tote their wares among high school students.

We find that some of our investigations have been frustrated, indeed aborted, because of the fact that we think that we are on a proper investigation involving CDS substances, involving the hard drugs, and find in fact they turn out to be aborted, because we are talking about look-alike drugs.

You can imagine the significance, at best frustration that we suffer as a result of that. And at the worst, the enormous amount of taxpayers' money, the enormous waste of time and energy on this type of investigation, because we are dealing with look-alike drugs, and we didn't know it at first.

As to present legislation, on the books of New Jersey, both in New Jersey and nationally, virtually anyone can obtain a registration form at the price of a small fee to manufacture or to wholesale look-alike drugs.

The difficulty there, of course, is that people in Jersey, we find, with extensive criminal backgrounds in perhaps even narcotics appear to be engaged in these activities.

The New Jersey statutory provisions parallel Federal food, drug and cosmetic law provisions, and that is, they do require registration, but it is not true licensing as you and I have come to understand that term, and further there are no criminal background checks required.

The State of New Jersey through the prosecutors of this State and under the aegis of Mr. Mulvihill and Mr. Falcone may have so testified this morning, we are proposing legislation. That legislation would penalize the manufacture and the sale of look-alike drugs as substitutes for CDS.

They would impose a prison term and a heavy fine.

We support that, I as attorney general, as a principal law enforcer in the State, support that legislation. It is wisely conceived

Further, I don't think we can do anything effective without national legislation. It seems to me New Jersey is one of 50 States, and the same problem is existent elsewhere. We would encourage Federal legislation to encourage a national effort.

We run into the specter of, and the accusations of, too much regulation, and you ought to cut down.

We have seen a resurgence of something which I heard termed a laissez-faire philosophy; and in this type of situation where the health and well-being of the Nation is at stake, I would opt for regulation rather than for a laissez-faire approach, leave-them-alone approach which jeopardizes the health of the young people of our Nation.

Mr. ZEFERETTI. Thank you very much.

[The prepared statement of James R. Zazzali follows:]

PREPARED STATEMENT OF ATTORNEY GENERAL JAMES R. ZAZZALI

Chairman Zeferetti, Members of the Committee, Ladies and Gentlemen, I am pleased to come before you this morning to discuss the disturbing problem of so-called "Look-Alike" drugs. I hope that dialogue generated here today will continue and eventually lead to a solution to this problem. The health and well-being of our youth are at stake, and they deserve our wholehearted efforts to remedy this problem.

The problem with "Look-Alike" drugs is that many citizens react with a "so what" attitude, believing the problem to be innocuous. While the problem is not of the same dimension as some hard drugs, it is a serious problem nonetheless and one which must be addressed.

For the purpose of illustrating the problem, imagine two columns. Under Column A is a list contaiing aspirin, caffeine, ephedrine and phenylpropanolamine (PPA). Under Column B is listed marijuana, barbiturates, amphetamines and heroin. What is the difference between Column A and Column B? Under existing law, the manufacturing and wholesaling of substances listed under Column A are virtually non-regulated, while the manufacturing and wholesaling of substances contained under Column B, those being controlled dangerous substances, are strictly regulated. Rather than concentrating on the differences between the substances listed under each of the columns, the problem we are discussing here today arises from the similarities existing among all substances mentioned. Namely, each of these substances is a drug which, when abused, can create serious health problems. Further, the non-regulated "Look-Alike" drugs are being peddled to our youth at exorbitant prices through a chain of ruthless manufacturers, wholesalers and dealers just like any type of controlled dangerous substance. The names of the drugs may change, but the game is the same. Wholly mercenary motivations dictate the actions of the profiteers while our youngsters out of either naivete or emotional weakness fall prey to another false symbol of sophistication.

More tragically, some of our youngsters have died as the result of ingesting pseudo-amphetamines and other such pills. The fact is that "Look-Alike" drugs, when taken in heavy doses, can among other things cause heart or respiratory failure.

Recent articles in Newsweek Magazine and People Magazine have reported the unfortunate deaths of several teenagers attributed to overdoses of various "Look-Alike" drugs.

My office has recently been in contact with several County Prosecutors' Offices and police departments throughout the State to determine the extent of the "Look-Alike" drug problem in New Jersey. While the overall magnitude of the problem has not yet been determined, several conclusions can be drawn from the information received thus far, those being:

(1) Large quantities of "Look-Alike" pills including pseudo-amphetamines have been uncovered in various counties throughout the State.

(2) Several persons in the State operate very profitable businesses in the sale of "Look-Alike" pills. Some of these businesses, and several others from outside New Jersey, freely advertise their products in brochures and flyers often distributed to high school students.

(3) With increasing frequency law enforcement agencies making seizures in drug investigations are being "burnt" by the seizures of "Look-Alike" pills. In such cases, the entire investigation involving the utilization of extensive resources is frustrated and usually terminates without a conviction.

The problem goes beyond the rip-off of the consumer, who may pay as much as $2.50 for a capsule worth only a few cents. According to information attained in other jurisdictions, the drugs are frequently sold to children as young as 10 years old, for whom such high concentrations, particularly of caffeine, can be lethal. Six deaths in Illinois, several of them children, have been attributed to "Look-Alike" drugs. In addition, even if a child is brought to an emergency room by a parent or

87-601 O - 82 - 6

other adult who can furnish a capsule similar to that taken by the child, the child is often not given the proper treatment. Because the fakes are skillfully made, it takes a pharmacist to see the difference between them and the drugs they imitate. Emergency room staff, therefore, often treat the individual for an overdose of what the drug appears to be, not what it really is.

Under present New Jersey law, virtually no action can be taken to limit the manufacture and wholesaling of drugs that are not controlled dangerous substances, particularly those drugs which can be sold without a prescription, such as aspirin and caffeine pills. Virtually anyone, even persons with extensive criminal backgrounds for narcotics offenses, can engage in the business of manufacturing noncontrolled substances by completing a registration form and paying the statutorily required fee. In this regard, New Jersey's statutory provisons parallel those in the Federal Food, Drug and Cosmetic Law which simply requires registration but not true licensing of drug manufacturers engaged in interstate commerce.

The County Prosecutors Association in conjunction with the Division of Criminal Justice has formulated proposed legislation which would penalize the manufacture and sale of "Look-Alike" drugs as substitutes for controlled substances. It has become emphatically clear that virtually anyone and everyone should not be permitted the opportunity to manufacture and distribute drugs. Legitimate drug manufacturers and wholesalers need not fear and should welcome the increased statutory requirements. But those who traffic in the "Look-Alike" drug market as a quick money proposition without regard for the safety of the consumer should be subject to a criminal prosecution exposing the defendant to a prison sentence and a high fine. It is anticipated that the proposed legislation which I have outlined should be ready for introduction in New Jersey State Legislature in the near future.

While New Jersey can do its best to regulate the manufacturing, distribution and sale of all drugs, and vigorously attempt to enforce such laws, our efforts will have little impact without full and complete cooperation from other States and the Federal Government. Our experiences of the past in combatting the illicit manufacturing and trafficking of controlled dangerous substances demonstrates the need for nationwide cooperation. I hope the Federal Govenment and other States will also find it fitting to address the problem of "Look-Alike" drugs with whatever action is required.

Mr. ZEFERETTI. One of the things we have learned this morning is to get the kind of priority necessary for law enforcement to do their job is a very difficult one. With the drug trafficking as it is today, it seems more important for law enforcement officers to worry about illegal narcotics rather than look-alike drugs.

But we find also that the look-alike issue has to be met, because these pills and capsules, as you just indicated in your testimony, are causing harm and death. I think by not making distribution of this product a crime, we are perpetuating this problem and we are also not doing anything to inform people that there are these substances that could cause death or permanent injury. You had the good fortune to have a doctor knowledgeable about your problem. But there are many young people and adults that do not know the difference between one drug or the other, or how a particular drug could affect them.

They don't know whether they have bought a helpful over-the-counter drug or a look-alike recommended by another friend who says "Hey, that helped me and it could help you, too."

Public awareness is something in which we have to get involved. This will get you the priority necessary, so you will be able to get the manpower and the tools necessary to fight this problem.

I am very frustrated and concerned after listening to some of the testimony. We had two distributors of these products testify that they received their registration certification by paying $100. Nobody knew who they were or did any check into their background. They are two young men working off the back of a truck that can do anything they wanted to do, without anybody knowing

who they were, where they came from, who they are dealing with, or from where they were getting their products.

Also, it is a very curious factor that no one knows where they get the money to purchase the products or pay for the advertisements in the school papers. Well, it scares the heck out of me.

You could help us by helping other legislators in this county and in this State to formulate that kind of registration process that can be meaningful by requiring a background check into the people seeking a certificate and more importantly to require information on how these drugs are going to be distributed.

This may be on the surface something that everybody feels they should have, but I surely would like to find out just who these people are. There may be many legitimate people in this business, and I am only after the ones that I feel can do harm.

Mr. ZAZZALI. The legitimate manufacturers and wholesalers have nothing to worry about. We are only concerned about those who traffic in this sort of thing illegally and are seeking to exploit our people. You are correct in terms of the awareness issue which we opened up on. It does not have the sexual quotient that other issues have. I am thinking, Congressman Guarini, of an analog here, a parallel here, the sweat shop problem. I know that it is an issue in the northeastern quadrant of the State you are concerned about. It does not have the appeal of a casino question, of street crime and violent crime issues which are perhaps more important in the balancing, but nevertheless, this should be a priority, and it is the job of all of us to make the public a little more aware of it.

Mr. ZEFERETTI. We are here to help in that effort, because I don't know how many men you can assign on a day-to-day basis into law enforcement. You are responsible for everything else and also with budgetary constraints, I know it is kind of a difficult task. But to get priority has always been a difficult task, whether you are dealing with this issue or jails or the criminal justice system. To get people to understand, you need that kind of priority. Sometimes it is very, very difficult.

That is why we are here, to bring that public awareness here, to tell people there has to be a priority given to this issue, because we are dealing with a substance that could lend itself to devastation.

I would like to add our arm of assistance and say to you, if there is legislation on the Federal level or even regulations that you feel could impact on the problem, I would like you to share them with us. This committee is concerned. We would take any proposals under advisement. We are interested in a goal of stopping this situation.

We are a select committee with about 22 jurisdictional committees that we answer to, and we have that oversight responsibility. We can be helpful in moving legislation through the legislative committees.

I would like to help you, but at the same time, I am asking you to help us too, because it is essential that we work together.

Mr. ZAZZALI. Thank you.

Mr. GUARINI. I would like to thank you for your very clear statement.

I have a sense of, after listening to a number of people who have testified from the Federal and State level, that there could be a

better awareness even among themselves, as well as the public, that the educational process is very important, and we do have to have cooperation between the local, State, and Federal levels of Government to be effective in dealing with this particular problem.

I was very interested in the fact that there was an attorney general's meeting in Chicago that was going to address itself to this problem. Is there anything you could relate as far as what the attorney generals intend to do, sir? Were you there?

Mr. ZAZZALI. I was at the attorney general's meeting in May, but I missed the one in Chicago. I don't know what the outcome or what was discussed at that meeting, but Jim, if you can remind me, it would be easy enough today to find out what was discussed out there, and I can let you gentlemen know.

Mr. GUARINI. Fine, we certainly feel what you have said has been very helpful, and thank you for taking time out of your busy day to come down here.

Mr. ZEFERETTI. Mr. Jeff Hoyak and Dr. Arthur Zampella, please step forward.

Would you like to identify yourselves?

TESTIMONY OF DR. ARTHUR ZAMPELLA, WEST MILFORD YOUTH AND FAMILY ADVISORY COUNCIL, WEST MILFORD, N.J.

Dr. ZAMPELLA. My name is Dr. Arthur Zampella, I am an M.D. and serve as a school physician, police, and fire surgeon, and president of the Board of Health in West Milford Township, the largest township in New Jersey.

I am also a licensed health officer, and a licensed laboratory director.

Shall I proceed?

Mr. ZEFERETTI. We have your statement, and it will be made part of the record in its entirety.

Dr. ZAMPELLA. I am conscious of the fact that my last name starts with a Z.

I am glad to see that hearings on this matter of look-alike drugs are taking place, and this one in New Jersey, and specifically in Jersey City.

New Jersey, one of the original 13 States, was a major battleground of the American Revolution, being the scene of over 100 battle engagements. We are in the midst of another battle presently, this one on the drug scene. Only 13 States have laws against look-alikes. New Jersey is not one of them. A Federal law is more desirable, enforceable, interstate, and uniform. We congratulate Congressman Leo Zeferetti, chairman of the Select Committee on Narcotics Abuse and Control and his associates, including Congressman Frank Guarini, on contemplating such important Federal legislation.

It is also appropriate for this hearing to be held in New Jersey which, in production of pharmaceuticals, ranks first, and is second in chemicals. New Jersey is a productive State, "A State of Surprise," as described in the prestigious National Geographic issue of November 1981.

In the capacity of health board president, I had the honor of participating in the formation of the youth and family counseling

advisory board and a beautification committee in the township. With the intent of keeping our township "Beautiful and Clean," and as a concerned citizen and parent of five school-age children, I joined fellow citizens and neighbors, supported by the youth board, the PTA, churches, the board of education, and community service and businessmen's associations in a wave of moral indignation over the sales of look-alike drugs to the youth of our community, within and without the school system.

The drug problems of the cities have become those of the suburbs also. I had been shocked into action by blatant advertising at the school my children attend and on a large sign painted on both sides of a van parked on a main thoroughfare and near a school. Our keynote is crisis intervention advocacy and prevention.

We have been impressed by the increased suicide rate in the 15- to 19-year-old age group, that suicide is one of the top five causes of death in teenagers, that 10 percent of teenagers who take drugs will end up dead from drugs, that there has been a 24-percent increase in juvenile delinquency in the past 20 years, and that approximately 40 percent of the population is in the below-19 age group.

We responded in this way. We regarded these sales as threatening the health of the youth of our community in that they contain potentially harmful ingredients such as caffeine, ephedrine, phenylpropanolamine, and which lend themselves to easy abuse, especially to those individuals who have diabetes, hypertension, hyperthyroidism, or cerebrovascular disorders.

Caffeine is regarded as an analeptic or central nervous system stimulant, ephedrine and phenylpropanolamine as adrenergic, that is, having an action like adrenalin, and doxylamine is classified as an antihistamine and used for insomnia.

They are variously misrepresented by sellers, not legitimate retail pharmacists, who set themselves up for fringe marketing, who appeal to this market looking for quick, easy, and lucrative sales, hawking them using descriptions such as "Uppers and Downers," "Stimulants," "Working all night?," "Burn off weight," "Party 'til morning?," "Drive straight through?"

Descriptions of the manufacturing and sales of these products and possible harmful effects, including cerebrovascular accidents or strokes, have been the subject of various network television programs, radio, newspaper, magazine and medical reports. We deplore this proliferation in recent years of distributors from a few to over 120.

Abusers of these substances may increase the dosage in order to increase the stimulating or depressing central nervous system effects to a point where they may exceed the safety or tolerance level, risking harmful effects.

Sellers may misrepresent or imply that these are controlled drugs, and being the "real thing," because of the fact that these products are made to resemble in color and shape and are even marked with misleading legends to suggest more potent and potentially dangerous controlled substances, such as Quaaludes, barbiturates, and amphetamines. The abuser may switch, knowingly or unknowingly, to the actual controlled substance, seeking greater stimulation or sedation, still at the larger dosage, and increase the

potential for damage or death with these "time bombs." Look-alikes are advertised in drug culture publications.

The promotion of the cultural practice and philosophy of "popping a pill" for whatever ails you and using it as a "crutch" is deplored. Prescriptions should be required.

Control of controlled substances is complicated by virtue of the fact that investigators are apprehending individuals possessing look-alikes which are confused in appearance with the real thing. As such they may represent a "smoke screen" hampering investigation of traffic in hardcore narcotics. The West Milford police department has received numerous calls from departments throughout the metropolitan area seeking clarification of look-alikes found on suspects.

Also advocated is the nonissuance of drug distributor's licenses to individuals with questionable backgrounds, records of drug abuse convictions, and with lack of professional expertise in an area of activity which is subjected to largely inadequate inspection and regulation. Violations are numerous, including retailing by distributors and lack of regulation of so-called retailers.

In general, the use of look-alikes, even as pertains to other over-the-counter and prescribed medications seems regrettable and an intrusion into the patent and manufacturing rights of the parent company and a violation of integrity in business.

In conclusion, I should like to quote from the legend on the petition which is being widely circulated and signed in our community as follows:

We, the undersigned, wish to express our desire that there be legislation passed to make illegal on a Federal, State and local level, the advertising and sale of look-alike drugs in all forms; further that the licensing requirements for the issuance of wholesale drug licenses be revised and strengthened to prohibit the issuance of any drug license to any persons with a record of drug convictions and to prohibit misrepresentation, sales to minors and other unauthorized individuals.

Mr. ZEFERETTI. Thank you, Doctor.

[The prepared statement of Arthur D. Zampella follows:]

PREPARED STATEMENT OF ARTHUR D. ZAMPELLA, M.D.

"LOOK-ALIKE" MEDICATIONS

I am glad to see that one of the first congressional hearings on the abuse of "Look-Alike" drug preparations is taking place in New Jersey and, specifically, in Jersey City.

New Jersey, one of the original thirteen states, was a major battleground of the American Revolution, being the scene of over 100 battle engagements. We are in the midst of another battle presently, this one on the drug scene. Only 13 states have laws against "look-alikes." New Jersey is not one of them. A Federal Law is more desirable, enforceable, interstate and uniform. We congratulate Congressman Leo Zeferetti, Chairman of the Select Committee on Narcotics Abuse & Control and his associates including Congressman Frank Guarini, on contemplating such important Federal Legislation. It is also appropriate for this hearing to be held in New Jersey which, in production of pharmaceuticals, ranks first, and is second in chemicals. New Jersey is a productive state, "A State of Surprise," as described in the prestigious National Geographic issue of November 1981.

I am pleased to be in Jersey City where I was born and where I spent my early years. My family is still strongly represented here, one brother being a Chief Judge and another a school principal, and still another having been a pharmacist here, interestingly enough, considering the topic we are discussing.

I serve as school physician, police and fire surgeon, and President of the Board of Health of West Milford Township, the largest Township in New Jersey, located in northwest New Jersey in Passaic County. In the capacity of Health Board President,

I had the honor of participating in the formation of the Youth and Family Counseling Advisory Board and a Beautification Committee in the township. With the intent of keeping our township "Beautiful and Clean", and as a Concerned Citizen and parent of five school age childern, I joined fellow citizens and neighbors, supported by the Youth Board, the P.T.A., churches, the Board of Education and Businessmen's Associations in a wave of moral indignation over the sales of "look-alike" drugs to the youth of our community, within and without the school system. The drug problems of the cities have become those of the suburbs also. I had been shocked into action by blatant advertising at the school my children attend and on a large sign painted on both sides of a van parked on a main thoroughfare and near a school.

We regarded these sales as threatening the health of the youth of our community in that they contain potentially harmful ingredients such as caffeine, ephedrine, phenylpropanolamine, and which lend themselves to easy abuse, especially to those individuals who have diabetes, hypertension or cerebrovascular disorders.

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Mr. ZEFERETTI. Mr. Hoyak.

TESTIMONY OF JEFF HOYAK, EDITOR, THE ARGUS, WEST MILFORD, N.J.

Mr. HOYAK. My name is Jeff Hoyak. I am the managing editor of the West Milford Argus newspaper. I am the author of the article.

I am here to address the community reaction and concerns to the existence of an alleged drug operation in West Milford that is

dealing in pharmaceuticals, the two representatives that spoke here earlier.

Mr. ZEFERETTI. We have your statement, so you may summarize if you like.

Mr. HOYAK. I will emphasize portions of the statement which address the community reaction.

The advertisement van which you have a picture of, it stirred up most of the commotion.

This bald-faced advertisement of drug sales caused somewhat of a clamor in the Apshawa section of West Milford, prompting First Ward Councilman Peter Gillen to publicly vow at a meeting, without specifically naming D. & E. Pharmaceuticals, that he would "stop the sale of phony drugs in West Milford."

Community reaction was as follows. Concurrent with and in the wake of an article published in my newspaper detailing the look-alike pill controversy, several groups in the township swiftly voiced concern and alarm over the situation and took positions or made statements against the alleged sale of look-alike pills in the township.

The West Milford zoning administrator ordered the Organs to remove their advertisement van within 5 days because it was in violation of a zoning ordinance stipulation that trucks cannot be parked in residential zones. The van has since been removed from its prominent position, to the rear of the property, but the Organs received a summons on Wednesday to remove it from the yard entirely because it can still be seen.

The board of education on September 28 agreed to support legislation banning look-alike pill sales. The West Milford Council of PTA's, the West Milford Business Association, and the newly formed youth and family counseling advisory committee have all come out, either officially or through a spokesman, against look-alike drug sales and in favor of legislation banning such sales.

In closing, I would like to state that even if these wholesalers are not peddling look-alike drugs, I perceive the existence of a business which caters largely to a drug-oriented crowd to be anathema to a conservative community like West Milford, whose distaste for the operation would be comparable to that for an adult book store or porno movie house.

[The prepared statement of Jeff Hoyak follows:]

PREPARED STATEMENT OF JEFF HOYAK

I first became aware of the possibility of a look-alike drug problem in West Milford last year, when a teacher in the West Milford school system informed me that the district's teachers had been advised by a West Milford police detective of the possible sale of caffeine pills to school students by local drug wholesalers.

I called the detectives and was advised that the operation was wholly legal and efforts to publicize it may have the adverse effect of attracting more students to the business as customers.

The issue surfaced again in September when D & E Pharmaceuticals of West Milford, licensed wholesalers of non-prescription drugs, placed a van garishly advertising the sale of stimulants in front of the residential home from which the business is legally operated.

This bald-faced advertisement of drug sales caused somewhat of a clamor in the Apshawa section of West Milford, prompting First Ward Councilman Peter Gillen to publicly vow at a meeting, without specifically naming D & E Pharmaceuticals, that he would "stop the sale of phony drugs in West Milford."

The publication of this statement in my newspaper angered D & E owners Eric and Denise Organ, a very pleasant and friendly young couple who invited me to tour their operation. I did so and saw no blatant evidence of look-alike drug manufacturing or sales on the premises (as well I wouldn't since they knew I was coming) and I was assured by the Organs that their business was legitimate, and shown proof that they were licensed and had passed federal inspection. The Organs also assured me that although the law does not prevent them from doing so, they do not sell their stimulant combinations of caffeine, phenylpropanolamine and ephedrine to minors by their own moral choice.

However, during the interview, I was shown advertisements placed by the Organs in drug culture magazines such as High Times and California Green magazines, which Lucius Bowser, acting chief of the N.J. Department of Health Drug Control Program told me was "kind of strange" because the Organs' license prohibits them from selling to the ultimate users of the drugs. Eric Organ also maintained that he spends a lot of money on advertising to educate people against the misuse and black market distribution of these drugs. Organ failed to produce any evidence of "educational" advertising, then admitted when pressed that a list of the ingredients in the drugs constituted the "educational" aspect of the newer ads he has taken out.

Robert Gilmartin, principal of West Milford High School, told me that pills similar to the ones sold by the Organs have been found in high school lockers and on the high school premises.

The Organs claim they spend a lot of money on "tooling" devices to prevent their products from resembling amphetamines. However, one of their business cards, which was procured by me from Dr. Arthur Zampella and which I had seen circulating around the township previously, clearly displays pictures of pills which resemble amphetamines and advertises the sales of "uppers and downers." The Organs contend the card is out of date.

The Organs are not the only licensed non-prescription drug wholesalers in West Milford. Mark and Daria Warner of Upper Greenwood Lake also hold a Department of Health license. Police and the Passaic County Prosecutor's Office confiscated 15,000 caffeine pills from the Warners but were forced to return them when the pills were found to contain no ingredients in violation of the Controlled Dangerous Substances Act.

Law enforcement officials have told me of their frustration in trying to control look-alike drug sales, contending that they are hamstrung by loopholes in the statutes which permit these sales to take place unabated.

Concurrent with and in the wake of an article published in my newspaper detailing the look-alike pill controversy, several groups in the township swiftly voiced concern and alarm over the situation and took positions or made statements against the alleged sale of look-alike pills in the township.

The West Milford zoning administrator ordered the Organs to remove their advertisement van within five days because it was in violation of a zoning ordinance stipulation that trucks cannot be parked in residential zones. The van has since been removed from its prominent position. The Board of Education on Sept. 28 agreed to support legislation banning look-alike pill sales. The West Milford Council of PTAs, the West Milford Business Association and the newly formed Youth and Family Counseling Advisory Committee have all come out, either officially or through a spokesman, against look-alike drug sales and in favor of legislation banning such sales.

Mr. ZEFERETTI. I want to personally thank you for this article in the newspaper. It produces public awareness in the community. I don't feel that the look-alike problem would have received any exposure at all, if not for articles such as yours. It is a situation that must be recognized and attacked.

From your investigation for your article, do you know if the truck selling these look-alike drugs and parking in the vicinity of the high school, is selling to young people on a retail or wholesale basis?

Mr. HOYAK. I could read the statement from the West Milford principal, who told me pills have been found in high school lockers and on high school premises, although they insist they do not sell to minors.

Mr. ZEFERETTI. They insist that they distribute on a wholesale basis, and they do it through the mails.

Again I want to commend you for writing the article, and I would suggest that you stay with the issue and with the council that is working as an advisory board in the community. Through these efforts attention will be brought to the situation and possibly it may be stopped.

I also think community action and education is a meaningful and effective manner to fight this problem.

Mr. Guarini.

Mr. GUARINI. As a matter of curiosity, does the problem also involve a mix with marihuana in the school system and with other hard drugs that are used?

Is this part of the drug ethic that is presently in our school system, or would you say it is disassociated?

Mr. HOYAK. I really don't feel qualified to answer that question.

Mr. GUARINI. Would the people that are selling these look-alike drugs be the same people that would be pushing marihuana and other substances in the school system in your opinion?

Mr. HOYAK. Again, in my statement, the Organs are not the only licensed nonprescription drug wholesalers in West Milford. Mark and Daria Warner of Upper Greenwood Lake also hold a department of health license. Police and the Passaic County Prosecutor's Office confiscated 15,000 caffeine pills from the Warners but were forced to return them when the pills were found to contain no ingredients in violation of the Controlled Dangerous Substances Act.

Mr. GUARINI. There is a connection.

Doctor, do you want to make any statement?

Dr. ZAMPELLA. I have a copy of one of the labels on the bottle, do you have that information on hand presently?

Mr. ZEFERETTI. What kind of information?

Dr. ZAMPELLA. It indicates even an awareness on the part of the manufacturer, and the distributor who in turn sells these substances with the sale label, that there are hazards involved.

For example, the contents are listed, caffeine, 150 milligrams, ephedrine sulfate, 25 milligrams. Warning: Do not take if you suffer from heart disease, diabetes, et cetera.

Keep out of reach of children, not to be used for pregnant women and elderly persons. Tolerance and habitation may occur with prolonged use, avoid driving while taking, and the contra indications, and a list of symptoms that might indicate potential illness.

It says avoid use when sleep is desired and if the following symptoms——

Mr. ZEFERETTI. May I interrupt you, because it is not a question of people reading those labels.

It is a question of people distributing that kind of pill to those that don't know the difference between what the dosage is, what it should be, and the type of pill.

It is really a question that these pills are falling in the wrong hands and people making a profit out of someone else's ability to produce something that may be in its proper form a legitimate kind of a substance, but overall, could be disastrous to someone else.

They are not interested in what is in the label or what the symptoms might be, but more interested in the dollar sign.

Mr. GUARINI. Usually they are clever enough to not get involved in the false labeling or false advertising, smart enough not to run afoul of the FTC.

I want to thank you as an old friend of the family for your contribution and dedication, and also Mr. Hoyak who really spotlighted the problem in the press, and has really been very, very helpful in bringing this to the surface, and I thank both of you for being most patient for being the last witnesses that we have.

Mr. ZEFERETTI. I will call Ms. Geraldine Silverman, chairman, drug awareness committee from Millburn, N.J.

Welcome, Ms. Silverman.

TESTIMONY OF GERALDINE SILVERMAN, MILLBURN CONFERENCE OF PARENTS AND TEACHERS, CHAIRMAN, DRUG AWARENESS COMMITTEE

Ms. SILVERMAN. I am on the board of directors of the National Federation of Parents for a Drug-Free Youth.

We are a group of parents that united throughout this Nation, because we are concerned for the youths of this Nation.

America's greatest natural resource is its youth. It is not its gold, oil, water, or anything else. We must realize that the youths of the Nation, whether this is a throw-away generation or not, will predict our future. Many nations do consider their youths as their number one priority.

I also wear the cap of being a drug awareness, not abuse, awareness, chairman, because any use of any drug without a specific doctor's recommendation, gentlemen, especially for youngsters and without parents' knowledge is abuse.

I am the drug awareness chairman of the Millburn Conference of Parents and Teachers, and also a representative for the New Jersey Congress of Parents and Teachers representing 300,000 parents in the State.

I think that you have asked some of these gentlemen what their profit was in 1 year, the growth of their business.

The reason that you have held, or the very fact that you have held these hearings, has brought a 100-percent recognition to a very imperative problem, not only one of look-alikes, but to the entire drug scene, because none of these things are independent.

It is a whole conglomeration and picture that you have painted. You have really picked up the ball. It is a warning to this Nation of what is happening, and the very fact that you have held these hearings will go a long way.

I have been invited with 19 other members to meet with Mrs. Nancy Reagan at the White House on November 9, 1981. That will be 2 weeks from today. I will meet with other members of the National Federation of Parents. We began a movement 3 years ago. Look-alike drugs will be on top of my agenda.

How can we help? We do need Federal legislation. There is no two ways about it. These types of people, the pill pushers and paraphernalia merchants are all one in the same ilk. They have gone into the holes and cracks of the law to make, as you pointed out, to make a buck.

They have appealed to the most innocent and most gullible of all, our youngsters.

Let us look back when we were teenagers, and we heard a loud, a tremendous message in this Nation, "Do it," smoke cigarettes. "Smoke!" "Be a part," "Everybody does it." Today the message is, "do drugs."

It is an enormous problem.

The people that must be reached besides legislators are the parents.

I appreciate our Attorney General, and our prosecutor's presence here. It is important that these hearings are being held in New Jersey. I pointed out, it is not the fact that we lie between two States, New York and Pennsylvania, but we are one of four target States in the Nation for drug sales.

New Jersey is the most densely populated State in the entire United States. We are a prime market. They come in after our children in every way, shape, and form. It is absolutely incredible.

When I began in 1978, we did not have a heroin epidemic. In 1 year's time—through reports and hearings held by our select committee, and Congressman Zeferetti—we have learned that we have been inundated with, instead of 600 metric tons of heroin as at the height of the 1969–71 epidemic, we have now been inundated in 1 year, June 1981 with 1,600 metric tons. They are hitting us with the finest heroin they have. The drug merchants are hitting us with many things.

What disturbs me is the lack of knowledge on the part of physicians, teachers, educators, all of us. It must be pointed out that this is a brand new ball game.

Look-alikes is another way of introducing young people to drugs. There are two types of youngsters that you should really consider. One is the young jock.

We would all like to think that our children will not get into drugs. Rest assured we all would. Today everybody's children are very susceptible to the drug message.

I will tell you something that has helped me do my homework better. It is talking with young people in our high schools and junior highs. I also teach now voluntarily at least 3 or 4 days a week, in 5th and 6th grades throughout this State.

I do paraphernalia awareness programs for parents at least 3 to 5 nights a week.

The young people that I am talking to that supposedly are into athletics say stimulants enhance our athletics. "I can swim better if I can get an extra second of time, if I can run that extra mile 2 seconds faster on track, I can win."

"If I can skate just a little bit faster, I can break the State record." "I can wrestle a little better with a pill."

They see no harm in drugs. They are told that there is no harm in "legal" stimulants or look-alikes.

Yet we are seeing these children exhibiting negative signs, many coaches don't even know.

What is happening to that young person who is not a lawbreaker, who is being lured into performing with the help of look-alikes. There is a great danger in this.

What will result in 10 years from now?

Let's look at the youngster who is in the drug culture.

We talked about synergism. As Congressman Guarini pointed out, there is great danger in combining drugs. The October 1981 NJEA Magazine, Congressman Guarini, gives you a State assessment of drugs and alcohol in high schools in New Jersey. I also brought in an article from the New York Times. Congressman Zeferetti, this is an assessment from the New York Times of your State of New York right now. What is the synergistic effects on these youngsters who are combining drugs with marihuana and perhaps alcohol? These are the two No. 1 drugs in New York and New Jersey among our 15–18-year-old set.

What are the effects of all these drugs?

Today we had 12 tons of marihuana wash up on the shores of New Jersey, to be brought into New York. They are reaping the harvest, and sending it up from Colombia.

Many people are not aware that there are dry times for marihuana, and that is when they push pills on these kids.

We have a lot of problems. You have begun, and I can promise you on my part, I will bring it before the State PTA, the National PTA, and to the attention of the National Federation of Parents. We must take responsibility and join you hand in hand in your efforts and back you in every way, because it is up to parents. If we won't do it, who will?

Mr. ZEFERETTI. Thank you very much.

This will be made part of the record, and your exhibits here will be made part of the record also.

[The information follows:]

MILLBURN CONFERENCE OF PARENTS AND TEACHERS

DRUG AWARENESS COMMITTEE 1980–1981

PURPOSE OF COMMITTEE

The overall purpose is to diminish drug and alcohol use among children and adolescents through Parent Awareness Programs.

We believe that a child's parents are his best bulwark against drug involvement.

We also believe that the universal instinct of parents to protect their young is society's bulwark against the expansion of the commercialized drug culture.

We believe that the most innovative and effective helpers for parents who are trying to cope with adolescent drug and drinking problems are other parents.

We believe that parents have many more resources and much more muscle than they realize when they are up against unhealthy social and peer pressures among their children.

We believe that the best way for parents to discover those resources and utilize that muscle is through communication and cooperation with other parents.

We believe that children have the most to lose from premature drug usage and the most to gain from strong, concerned and loving anti-drug involvement by their parents.

We believe when parents band together to prevent unhealthy or illegal adolescent behavior, they can create positive parental peer pressure to counteract or even reverse negative adolescent peer pressure.

GOALS

To educate parents about the current trends in drug and drinking behavior among children and adolescents.

To educate parents on the effects of legal and illegal drugs on particular stages of adolescent development.

To educate parents about the forces in the local community and in the larger society which encourages youngsters to use intoxicants for fun and escape.

To help parents bridge the gap between parental awareness and adolescent realities regarding the drug and drinking scene.

PLANS

The PTA plans to provide drug and alcohol dissemination service by gathering and disseminating information on: The latest medical and psychological findings on the effects of drugs on children and teenagers; current patterns of drug and alcohol use among children and teenagers; social and cultural pressures that encourage children and teenagers to use drugs; institutional and legal efforts being made to prevent usage, to reduce drug supplies and to prosecute drug traffickers; and any other facts pertaining to drug and alcohol use among children and teenagers.

Committee members include Mrs. Geraldine Silverman, Chairman; Mr. Robert Pearson, Director of Health and Physical Education; Mrs. Elaine Becker, Conference Representative; Mrs. Stephanie Andrees, Deerfield School; Mrs. Bernice Eisfeld, Wyoming School; Mrs Joan Engel, Short Hills School; Mrs. Barbara Sherman, South Mountain School; Mrs. Sheila Roth, Glenwood School; Mrs. Beverly Orel, Millburn Senior High.

Mr. ZEFERETTI. I would like to also thank you for helping us at the time that we went before Congress for the reconstitution of the committee. It was the National Federation of the Parents that helped us in our effort to have the committee reconstituted.

Before I close, I too would like to again thank Dr. Maxwell for the use of his beautiful facility, and for the courtesy extended to us and to my dear colleague, Mr. Guarini, for the hospitality of his community.

Thank you all, and we adjourn the committee.

[Whereupon, at 1:50 p.m., the committee was adjourned.]

[The following was received for the record:]

LEE C. ZEFERETTI, N.Y.
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U.S. House of Representatives
SELECT COMMITTEE ON
NARCOTICS ABUSE AND CONTROL
ROOM H2-234, HOUSE OFFICE BUILDING ANNEX 2
WASHINGTON, D.C. 20515

COMMITTEE PHONE 202-226-3040

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PATRICK L. CARPENTIER
CHIEF COUNSEL
ROSCOE B. STAREK III
MINORITY COUNSEL

December 2, 1981

Mr. Gene R. Haislip
Director
Office of Compliance and
Regulatory Affairs
1405 Eye Street, NW
Room 519
Washington, D.C. 20537

Dear Mr. Haislip:

On behalf of the entire Select Committee, I want to thank you for appearing at our October 26 hearing in Jersey City, New Jersey, to testify and answer questions about look-alike drugs. Your testimony was most valuable in helping us to understand the nature of the problems created by look-alike drugs and the Federal response to these problems. Please also express our appreciation to Mr. Tobin for appearing with you to answer questions.

To complete our hearing record, we would appreciate your written responses to the attached questions. Your answers will assist the Committee in formulating responsible recommendations for further action with respect to look-alike drugs.

Again, thank you for your important contribution to our hearing.

Sincerely,

Leo C. Zeferetti

LEO C. ZEFERETTI
Chairman

LCZ:ggc

Attachment

Questions for Mr. Haislip, DEA

1. What is the status of the model act DEA is drafting for concerned states to adopt? Has it been distributed to states yet? If so, please provide the Committee with a copy of the model act and any supporting or explanatory materials distributed with the act.

2. A number of state and local witnesses at our hearing in New Jersey urged that Federal legislation be adopted to make the manufacture, distribution and sale of look-alikes illegal.

   a. Do you believe that such authority is needed at the Federal level? If not, why not?

   b. Assuming such legislation is needed, what form should it take and which Federal agency should be charged with enforcing it?

   c. If DEA were given such authority, what problems would you encounter in trying to enforce it? For example, would your resources be adequate?

3. Have any DEA investigations resulted in the undercover purchase of look-alike drugs which were represented to be controlled substances? If so, did DEA refer the case to FDA for possible action under the Federal Food, Drug and Cosmetic Act?

4. Do you believe it would be useful for DEA agents to be authorized to make arrests for violations of the Federal Food, Drug and Cosmetic Act they encounter in their enforcement activities under the Controlled Substances Act? What problems do you foresee in such an approach?

5. What actions are you currently planning or undertaking with responsible drug manufacturers and other industry groups to control the look-alike trade?

6. In light of the widespread abuse of look-alike drugs and the health risks associated with ingredients commonly used in look-alikes, would it be appropriate to schedule ephedrine, phenylpropanolamine and possibly other look-alike components under the Controlled Substances Act? Should such substances be available only by prescription?

7. a. What impact have the FDA seizure actions had on the look-alike trade?

   b. Do you have any evidence or information to indicate that look-alike producers are altering their products to avoid legal problems under the FDA counterfeit statute?

8. Since the hearing, have you obtained any evidence or information that would indicate a problem with importation or clandestine manufacture of look-alikes?

9. Since the hearing, what steps has DEA taken with other Federal agencies to establish a formal interagency mechanism to monitor look-alike problems and coordinate Federal efforts against look-alike drugs?

U.S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

DEC 15 1981

The Honorable
Leo C. Zeferetti
U.S. House of Representatives
Washington, D. C. 20515

Dear Mr. Zeferetti:

Thank you for the opportunity to appear before your Select Committee on October 26 to present DEA's views on the look-alike problem. Be assured that DEA shares your concern over this despicable problem and within the framework of our legislative mandate and present resources, DEA will continue to strive to eliminate this problem.

Enclosed are DEA's responses to the questions which you submitted. If I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Gene R. Haislip, Director
Office of Compliance and
Regulatory Affairs

Enclosure

87-601 O - 82 - 7

1) The DEA Model Imitation Controlled Substances Act has been completed and is available upon request from DEA. Copies of the Act were distributed at a meeting of state Attorneys General held in Chicago, Illinois in late October. A copy of the model Act with commentary is attached.

2) a. At the present time, DEA sees no need for further Federal legislation concerning look-alikes. There appears to exist sufficient means at the Federal and state levels to effectively handle this problem. Actions taken by the FDA against look-alike manufacturers and by the U.S. Postal Service against many of the distributors, should have a significant impact. DEA's model Act can serve as a guide for states wishing to adopt uniform look-alike legislation. Local jurisdictions are best able to handle this problem at the user level. Agreements between DEA and capsule manufacturers have resulted in the manufacturers' refusal to sell capsules to companies using them for look-alikes. The possible use of the Federal Trade Commission's authority should be examined prior to any new legislation. If, after a period of time there is evidence indicating that the currently available measures at all government levels have been proven ineffective, then Federal legislation should be considered.

b. Based on our knowledge of the Food, Drug and Cosmetic Act, the actions taken by FDA under this Act against look-alike manufacturers and the purview of the Controlled Substances Act, it appears that the FD&C Act is most germaine to the issue. This suggests that if further legislation is deemed necessary, some amendment to the FD&C Act administered by the FDA may be most appropriate.

c. If DEA were given further authority to enforce new look-alike laws, there would be a considerable drain on our already limited resources, probably beyond our present capacity. The enforcement of look-alike laws would have to be prioritized and would take away resources from other serious drug abuse problems. Further, an overlap with the FD&C Act is likely if DEA were given enforcement authority over the look-alike manufacturers.

3) A number of DEA investigations aimed at dealers of controlled drugs have resulted in the purchase or seizure of look-alikes which were represented as controlled substances. None of these investigations involved look-alike manufacturers nor were look-alikes the target of these cases. Many of the capsules obtained as a result of these investigations were submitted for ballistics examination and found to have the same markings and general appearance as those confiscated by the FDA. DEA is working closely with the FDA in using this data to prepare testimony for use in support of the FDA actions against the manufacturers of look-alikes.

4) DEA agents do not have the necessary expertise to effectively enforce the regulations under the Federal Food, Drug and Cosmetic Act. Acquiring this expertise would be a time consuming, expensive and perhaps an inefficient process. The FDA has an existing regulatory arm which can determine whether such violations have occurred and take any appropriate action.

5) Letters have been sent to the three known United States' capsule manufacturers in an effort to solicit their aid. The Eli Lilly Company has agreed to refuse to sell gelatin capsules to manufacturers who will use them for look-alike products. Other capsule manufacturers have expressed a willingness to cooperate although it is not known if they have taken any positive steps as yet.

   Representatives of DEA, through the Voluntary Compliance Program, have spoken to the DEA-Industry, Distributor, Pharmacy and Practitioner Working Committees concerning look-alikes.

6) The information available concerning the ingredients in look-alikes indicate that they should not be placed under the Controlled Substances Act at this time. Specific findings concerning each individual substance must be made before a substance can be placed under control. Additionally, a scientific and medical evaluation and recommendation must be received from the Secretary of Health, Department of Health and Human Services, before a decision as to control can be made. DHHS has made no recommendation to control any of these ingredients nor in our opinion do any of these ingredients meet the necessary findings for control, based on our current information.

   Look-alikes, for the most part, are used because of their representation as and similarity to controlled products. If the present ingredients were placed under the CSA, the look-alike manufacturers would likely use other ingredients in their products. Further, the present components of look-alikes are common ingredients in many legitimate OTC and prescription products not subject to abuse. Placing the ingredients under control would place an undue burden on the manufacturers and distributors of these legitimate products.

   The determination of the need for prescription status for drugs falls under the purview of the FDA and is made independent of any scheduling decisions.

7) a. It is difficult to determine the impact of the FDA seizures at this time. A consent agreement to stop manufacturing look-alikes has been reached with at least one manufacturer and negotiations are under way with several others. It appears likely that the seizure of more than 15 million dosage units and 20 million empty capsules, as well as over one million dollars worth of equipment, will have a significant impact on the amount of look-alikes available if these seizure actions are upheld in court.

b. DEA has information that some producers of look-alikes are labeling their products as "not for human consumption" in an effort to avoid legal problems under the FDA counterfeit statute. Additionally, a recent report has indicated that some look-alike producers are marketing products which do not mimic any controlled product but which contain the same OTC ingredients. These products are reportedly advertised and represented in the same way as the look-alikes. The FDA seizure actions would have no impact on these products.

8) The clandestine manufacture and importation of "714" tablets are major problems to DEA. However, these "714" tablets contain methaqualone, a Schedule II controlled substance, which is diverted from international commerce, clandestinely tabletted in South America and smuggled into the U.S. These are not the same as the "714" look-alikes which contain noncontrolled ingredients and are manufactured and distributed in the U.S. DEA is unaware of any evidence of the clandestine manufacture or importation of look-alike products.

9) DEA, along with representatives of FDA, U.S. Postal Service, FTC and IRS have formed an interagency working committee to monitor the problem and coordinate and support each agencies' efforts in this area. Meetings have already been held in November and December.

MODEL IMITATION CONTROLLED SUBSTANCES ACT

Drafted by the

Drug Enforcement Administration

of the

United States Department of Justice

Prefatory Note

The wholesale vending of look-alike drugs has become a major, nationwide drug abuse problem. Look-alikes are tablets and capsules which are manufactured and imprinted to closely resemble or even duplicate the appearance of well-known, brand name controlled substances, but which contain only non-controlled over-the-counter drugs such as caffeine, ephedrine, phenylpropanolamine, acetaminophen, or some combination of these substances. Look-alikes are advertised as being body stimulants, alternative energy sources, or nighttime analgesics - the "safe," legal way to get high.

The number of look-alike wholesalers and distributors has grown from just a handful at the end of 1979 to more than 110 in June of 1981. The primary targets of this multi-million-dollar industry are college, high school, and even junior high school students. These youthful customers are being bombarded by advertising which extols these products as being "the most powerful stimulants available without a prescription." Most of the ads offer jars of 1,000 dosage units and suggest that purchasers can make high profits from resales. In the past several months, there has been a plethora of advertisements in the underground drug press, in music magazines, and even in the legitimate press as well as a flood of flyers and business cards on college campuses and in schoolyards across the country. Some wholesalers have expended tens of thousands of dollars on advertising, money they consider to be well-spent.

The recent proliferation of look-alikes has caused deep consternation among law enforcement authorities across the nation. Time, effort, and taxpayers' money have been expended and arrests have been made only to discover that the so-called drugs were actually noncontrolled substances. In some cities, so many cases have been dismissed that police departments are no longer buying pills or making dangerous drugs cases at all. Parents and community leaders have written to express their feelings of outrage and indignation at the way in which these substances are freely advertised and sold.

Look-alikes are touted as being completely safe and legal and consumers are advised to take several in order to get the full effect. Of course, the danger to a child who has been ingesting five or six caffeine pills and attempts the same thing with real amphetamines one day is obvious. More

insidious is the growing climate of acceptance of these substances among students as their sale and use become widespread. Of immediate concern, however, are recent reports of hospital emergencies and even overdose deaths caused solely by ingestion of look-alikes.

The DEA, for the reasons cited above, considers the manufacture, distribution and use of look-alikes to have a substantial and detrimental effect on the general welfare of American society, particularly on our youth. It is a problem which must be dealt with at all levels of Government. Efforts against the look-alike problem, however, must take into consideration the facts that the look-alike ingredients have a legitimate medical use, they are found in many of the more common over-the-counter products and when used as directed, they are generally not harmful. DEA has no jurisdiction over look-alike products under the Controlled Substances Act since only noncontrolled substances are involved. However, DEA does have a responsibility to combat drug abuse and considers the look-alike problem one facet of drug abuse. The distribution and sale of look-alikes, much as drug paraphernalia, encourages and contributes to the profiteering from drug abuse. Thus DEA has undertaken an initiative, similar to that used in the paraphernalia problem, against look-alikes. At the heart of this initiative is the Model Imitation Controlled Substances Act which is targeted to eliminate these undesirable enterprises through the application of regulations and civil and criminal penalties. A number of states have already enacted look-alike legislation. DEA applauds this action and encourages other states to do the same. The DEA Model Act will serve as a guide for states that wish to take legislative action against look-alike manufacturers and distributors.

MODEL IMITATION CONTROLLED SUBSTANCES ACT

Section 1. Definitions

a. The term "controlled substance" means a substance as defined in (insert appropriate citation for definition of "controlled substance" in State Controlled Substances Act).

b. The term "distribute" means the actual, constructive, or attempted transfer, delivery, or dispensing to another of an imitation controlled substance.

c. The term "manufacture" means the production, preparation, compounding, processing, encapsulating, packaging, or repackaging, labeling or relabeling, of an imitation controlled substance.

d. The term "imitation controlled substance" means a substance that is not a controlled substance, which by dosage unit appearance (including color, shape, size and markings), or by representations made, would lead a reasonable person to believe that the substance is a controlled substance. In those rare cases when the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance" (for example in the case of powder or liquid), the court or authority concerned should consider, in addition to all other logically relevant factors, the following factors as related to "representations made" in determining whether the substance is an "imitation controlled substance":

(1) Statements made by an owner or by anyone else in control of the substance concerning the nature of the substance, or its use or effect.

(2) Statements made to the recipient that the substance may be resold for inordinate profit.

(3) Whether the substance is packaged in a manner normally used for illicit controlled substances.

(4) Evasive tactics or actions utilized by the owner or person in control of the substance to avoid detection by law enforcement authorities.

(5) Prior convictions, if any, of an owner, or anyone in control of the object, under state or Federal law related to controlled substances or fraud.

(6) The proximity of the substances to controlled substances.

Section 2. Offenses

a. Manufacture or distribution - It is unlawful for any person to manufacture, distribute, or possess with intent to distribute, an imitation controlled substance. Any person who violates this section shall be guilty of a crime and upon conviction may be imprisoned for not more than _____, fined not more than _____, or both.

b. Distribution to a minor - Any person 18 years of age or over who violates Section 2a by distributing an imitation controlled substance to a person under 18 years of age is guilty of an aggravated crime and upon conviction may be imprisoned for not more than _____, fined not more than _____, or both.

c. Possession - It is unlawful for any person to use, or to possess with intent to use, an imitation controlled substance. Any person who violates this section is guilty of a crime and upon conviction may be imprisoned for not more than _____, fined not more than _____, or both.

d. Advertisement - It is unlawful for any person to place any newspaper, magazine, handbill or other publication, or to post or distribute in any public place, any advertisement or solicitation with reasonable knowledge that the purpose of the advertisement or solicitation is to promote the distribution of imitation controlled substances. Any person who violates this section is guilty of a crime and upon conviction may be imprisoned for not more than _____, fined not more than _____, or both.

e. Immunity - No civil or criminal liability shall be imposed by virtue of this Act on any person registered under the Controlled Substances Act who manufactures, distributes, or possesses an imitation controlled substance for use as a placebo by a registered practitioner in the course of professional practice or research.

Section 3. Forfeiture

(Insert designation of state civil forfeiture section) is amended to provide for the civil forfeiture of imitation controlled substances by adding the following after paragraph (insert designation of last category of forfeitable property):

"( ) all imitation controlled substances as defined by (list appropriate citation for this Act in the state's statutes).

Section 4. Severability

If any provision of this Act or the application of the Act to any person or circumstance is held invalid, the invalidity does not affect the other provisions or applications of the Act which can be given effect without the invalid provision or application and to this end the provisions of this Act are severable.

COMMENT

The Model Imitation Controlled Substances Act incorporates by reference certain definitions in the applicable State Controlled Substances Act, but does not attempt to incorporate or amend the definition of "counterfeit substance" in the State Controlled Substances Act. DEA believes it would unnecessarily confuse the issues to attempt to amend the definition of "counterfeit substance" in the State Controlled Substances Act. Therefore, the Model Act uses a new term of "imitation controlled substance" as the key to the Model Act.

DEA believes that many of the existing and draft State Acts which have sought to reach the look-alike problem have placed too much emphasis on the representations made by the seller of the substances. Hence, the DEA Model Act seeks to place emphasis on the "look-alike" nature of most of the substances involved to sustain the burden of proving a violation. The portion of the DEA Model Act which deals with "representations made" by the seller is not really intended to reach look-alikes in tablet or capsule form, but rather, is intended to reach those cases where powder or liquid is represented to be controlled substances. Most cases related to powder will involve alleged cocaine or heroin, and most cases related to liquid will involve alleged PCP or other hallucinogenic drugs.

The sections of the Model Act which deal with penalties, advertisement, forfeiture, and severability are framed from the pattern used in the Model Drug Paraphernalia Act, drafted by DEA in August 1979. As of October 1981, the Model Paraphernalia Act has been enacted by 23 states and many localities, and has been upheld at the state level by every Federal District Court and Appeals Court that has considered it. As in the Model Paraphernalia Act, the Model Imitation Controlled Substances Act leaves to each state the specific penalty to be inserted as a sanction for each of the criminal offenses proscribed by the Act.

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U.S. House of Representatives

SELECT COMMITTEE ON
NARCOTICS ABUSE AND CONTROL

ROOM H2-234, HOUSE OFFICE BUILDING ANNEX 2
WASHINGTON, D.C. 20515

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December 2, 1981

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Mr. William T. Murphy
Assistant Chief Postal Inspector
Office of Criminal Investigations
United States Postal Service
475 L'Enfant Plaza West, SW
Washington, D.C. 20260

Dear Mr. Murphy:

On behalf of the entire Select Committee, I want to thank you for appearing at our October 26 hearing in Jersey City, New Jersey, to testify and answer questions about look-alike drugs. Your testimony was most valuable in helping us to understand the nature of the problems created by look-alike drugs and the Federal response to these problems. Please also express our appreciation to Mr. Madden for appearing with you to answer questions.

To complete our hearing record, we would appreciate your written responses to the attached questions. Your answers will assist the Committee in formulating responsible recommendations for further action with respect to look-alike drugs.

Again, thank you for your important contribution to our hearing.

Sincerely,

LEO C. ZEFERETTI
Chairman

LCZ:ggc

Attachment

Questions For Mr. Murphy

1. Since the hearing what steps has USPS taken with other Federal agencies to establish a formal interagency mechanism to monitor look-alike problems and coordinate Federal efforts against look-alike drugs?

2. a. Please give us a current report on the number, nature and status of actions the Postal Service has filed against look-alike distributors? How effective do you believe these actions have been in controlling the look-alike trade?

b. Have any of your look-alike actions resulted in criminal prosecutions? If not, do you anticipate instituting any criminal actions?

3. In your view, what effect has the FDA seizure action had on the look-alike trade?

4. During the hearing you mentioned legislation, H.R. 3973, that could be of help to the Postal Service in look-alike and other investigations. What is the current status of that bill? Please explain what the bill would do and how it would help you.

5. Do you believe current Federal authority is sufficient to control the manufacture, distribution and sale of look-alike drugs? If not, what additional authority would ycu recommend?

OFFICE OF THE CHIEF POSTAL INSPECTOR
Washington, DC 20260

January 5, 1982

Honorable Leo C. Zeferetti
Chairman, Select Committee on
Narcotics Abuse and Control
U. S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your kind letter of December 2. I appreciate having had the opportunity to speak before your committee concerning the problem of look-alike drugs, and I am pleased to comment further regarding the Postal Service's efforts in this area. Your questions are addressed in the order in which they appeared in your letter.

1. Since the hearing on October 26, 1981, representatives of the Postal Inspection Service have attended two inter-agency meetings together with personnel from DEA, FDA, FTC and IRS. The first of these meetings dealt with the progress the involved agencies have made and identified some of the largest promoters of these drugs. It also set the stage for the second meeting, a more task-oriented working gathering. We plan to maintain open dialogue with associated agencies and meet at appropriate intervals.

2. (a) Thus far, we have initiated civil action (under Title 39, United States Code, §3005) against 41 promoters of look-alike drugs. Thirty-three of these promoters have gone out of business following False Representation Orders or Consent Agreements. Proceedings involving the other eight firms have not yet been completed.

   (b) No criminal charges have been initiated, although each investigation is considered a potential criminal violation.

The fact that an administrative complaint is filed and upheld is not a bar to later criminal proceedings; however, it is often more effective to take action which quickly removes the profit incentive than it is to become involved in a lengthy criminal investigation and prosecution. At present, I am unable to forecast which, if any, cases will result in criminal filings. Naturally, were a firm to violate a False Representation Order or Consent Agreement, the likelihood of criminal charges would be enhanced.

3. An evaluation of the effectiveness of the FDA's seizure action on the look-alike trade could best be made by the sefzing agency. The limited jurisdictional role of the U. S. Postal Service does not encompass the accumulation of information regarding manufacturing that would necessarily be important to the FDA.

4. Legislation was recently introduced in the Congress to amend Title 39, United States Code, §3005. The proposed legislation would also add a new provision to Chapter 4 of Title 39. The House version of the bill was introduced on June 18, 1981, as H.R. 3973. On June 22, 1981, S. 1407, an identical bill, was introduced in the Senate. The proposed addition to Chapter 4 is a new section which would authorize the issuance of an "Investigative Demand." This "Demand" would permit access to documents and objects relating to violations of any postal statute. The "Demand" authority would be similar to that already granted the Inspectors General of various federal agencies. Enforcement of the "Demand" authority would lie with the appropriate U. S. district court.

The bill would also amend Title 39, United States Code, §3005 to:

(a) Allow the Postal Service to obtain, at the promoter's place of business and upon payment of the advertised price, any product sold by mail. This facility would greatly reduce the time now lost in obtaining the product. Often the suspect firm incorporates a delay of as much as six weeks in its schedule for filling orders. The new procedure, by expediting the procurement and analysis of the product, would reduce the number of victims who fall prey to these promotions.

(b) Penalize ($10,000 fine per day of violation) persons who violate False Representation Orders. This monetary sanction is intended to discourage repeat violations. Any person against whom a penalty is assessed would have the right to judicial review in a U. S. court of appeals.

5. In Item No. 4, I highlighted pending legislation which, if passed, would greatly enhance the Postal Service's effectiveness in dealing with false and misleading mail order promotions such as look-alike drugs. Our efforts are, naturally, directed at the distribution systems and sales representations. The sufficiency of present authority to control manufacturing is a question better left to those agencies closer to the problem, viz., FDA.

Once again, I thank you for the opportunity to respond to your inquiries.

Sincerely,

W. T. Murphy
Assistant Chief Inspector
Criminal Investigations

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December 3, 1981

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MINORITY COUNSEL

Mr. Timothy J. Muris
Director
Bureau of Consumer Protection
Federal Trade Commission
Pennsylvania Ave. at 6th St., N.W.
Washington, D.C. 20580

Dear Mr. Muris:

On behalf of the entire Select Committee, I want to thank you for the written statement you submitted for inclusion in the record of our October 26 hearing in Jersey City, New Jersey, on look-alike drugs. I regret that you were unable to appear in person before the Committee to present your views.

As several weeks have elapsed since our hearing, we would appreciate a current report on the Commission's activities with respect to look-alike drugs. I have appended a series of questions relating to the Commission's action on look-alike drugs in this intervening period. We would appreciate your written responses to these questions which we will also include in the hearing record.

Your written testimony states, "...if the essence of the problem is drug abuse, the solution may not lie in the FTC's regulatory remedies." The misuse of look-alike drugs is certainly a drug abuse problem. The rapid escalation of look-alike abuse into one of the Nation's most serious drug abuse problems, however, is due primarily, if not exclusively, to the highly questionable business practices of producers and distributors whose products and advertisements serve no legitimate medical need but are purposely designed to deceive the public and promote the recreational use of drugs, particularly among young people. In short, both the products and the methods used to promote them would seem to fall squarely within the scope of unfair or deceptive acts or practices prohibited by the FTC Act.

The abuse of look-alike drugs poses serious risks of harm to the public. Controlling the trade in look-alike drugs requires prompt, concerted action by Federal, State and local authorities. In view of all the above considerations, I urge the Commission to exercise its authority to the fullest extent in cooperation with other agencies and officials to remove these products from the marketplace.

Sincerely,

Leo C. Zeferetti

LEO C. ZEFERETTI
Chairman

LCZ:ggn

Enclosure

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

BUREAU OF
CONSUMER PROTECTION

January 12, 1982

Honorable Leo C. Zeferetti
Chairman
Select Committee on Narcotics
Abuse and Control
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your December 3, 1981 inquiry in behalf of the entire Select Committee on Narcotics Abuse and Control. In your letter to me you asked five questions relating to events that may have occurred at the Federal Trade Commission (FTC) with respect to look-alike drugs since the October 26 hearings of the Select Committee. It is my understanding that you intend to introduce my response to these questions into the hearing record of the Select Committee. The following are your questions and my answers to your questions:

1. Since our hearing, what action have you taken on the FTC staff recommendation that the Commission authorize a formal investigation, including the use of compulsory process, into the look-alike industry? What action has the Commission taken with respect to this recommendation? Please explain the reasons for any actions taken by either you or the Commission. If no action has been taken, when do you anticipate a decision by the Commission?

Because of the increased involvement of the Food and Drug Administration (FDA) and the Postal Service in this area, the FTC staff members conducting the informal investigation of the look-alike drug industry deferred formally submitting their recommendations to me until they could evaluate the impact of these governmental activities on the look-alike industry. It is my understanding that staff is concerned that the Commission not allocate its limited resources to dealing with look-alikes if other federal agencies are adequately dealing with the problem. Because staff has not made any recommendation to me yet, I cannot anticipate what action I will recommend to the Commission, nor if or when the Commission will take action.

87-601 O - 82 - 8

2. Is the FTC participating in any interagency group established to monitor look-alike problems and coordinate Federal actions against look-alike drugs? If so, what other agencies are involved and how often does the group meet?

The FTC staff participates with the Drug Enforcement Administration, FDA, the Postal Service, and the Internal Revenue Service in monitoring look-alike problems. A working committee comprising representatives of each agency meets at least once a month.

3. Is the FTC continuing to monitor the look-alike situation?

Yes.

4. In your view, how effective has the FDA seizure action been in controlling the look-alike trade? Do you have any evidence or information to indicate that, as a result of the seizures, look-alike products are being:

   a. imported?
   b. manufactured clandestinely?
   c. altered to avoid legal attack based on any obvious resemblance to controlled drug products?

It is naturally our hope that the FDA seizures, the Postal Service proceedings, and the voluntary actions by manufacturers of raw materials used by the look-alike industry will be effective in controlling the look-alike trade. Staff advises me, however, that it is too early to tell. We do not have evidence at this time that look-alikes are being imported, manufactured clandestinely or altered to avoid legal attack. As I indicated in my statement to the Select Committee, our investigation to date has been informal and accordingly limited in the extent to which it has unearthed information of this kind.

5. If the appearance of look-alikes is, in fact, altered to no longer resemble controlled substances, would the FTC still have authority to take action against the commerce in such products?

This is a difficult question to answer in the abstract because the FTC's authority would depend upon the specific circumstances at hand. If, for example, a "non-look-alike" product were deceptively promoted or advertised, the FTC would retain jurisdiction. The FTC's jurisdiction would be less clear if such a product were marketed in a completely truthful manner which complied with all labeling and advertising requirements.

I hope that this is responsive to the questions of the Select Committee.

Sincerely yours,

Timothy J. Muris
Director

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SELECT COMMITTEE ON
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December 2, 1981

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ROSCOE B. STARKS III
MINORITY COUNSEL

Mr. Joseph P. Hile
Associate Commissioner for
Regulatory Affairs
Food and Drug Administration
1499 Parklawn Building
Rockville, Maryland 20857

Dear Mr. Hile:

On behalf of the entire Select Committee, I want to thank you for appearing at our October 26 hearing in Jersey City, New Jersey, to testify and answer questions about look-alike drugs. Your testimony was most valuable in helping us to understand the nature of the problems created by look-alike drugs and the Federal response to these problems. Please also express our appreciation to Dr. Tocus and Mr. Springer for appearing with you to answer questions.

To complete our hearing record, we would appreciate your written responses to the attached questions. Your answers will assist the Committee in formulating responsible recommendations for further action with respect to look-alike drugs.

Again, thank you for your important contribution to our hearing.

Sincerely,

Leo C. Zeferetti

LEO C. ZEFERETTI
Chairman

LCZ:ggc

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 09 1982

The Honorable Leo C. Zeferetti
Chairman, Select Committee on
Narcotics Abuse and Control
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in further reply to your letter of December 2, 1981, in which you address a number of questions to be made a part of the record for the hearing held on October 26, 1981, concerning over-the-counter (OTC) look-alike drug products.

I apologize for the amount of time it is taking us to respond to your questions; however, gathering the data you requested required the efforts of several different offices of the Agency.

I wish to thank you for asking the Agency to appear before your Committee to testify on the problem of the OTC look-alike drug products. I am sure the efforts of your Committee will have a significant impact on helping to bring this problem under control.

If I can be of further assistance, please let me know.

Sincerely yours,

Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

Enclosures

Question #1

In your statements before the Committee, you indicated that FDA's investigation of look-alike drugs was continuing and that FDA had not yet concluded whether any additional regulatory actions, including criminal prosecutions, were appropriate.

Question #1a.

Since the hearing, what additional regulatory action, if any, has FDA taken with regard to look-alike drugs?

Answer

In mid-January, Federal marshals seized approximately 597 pounds of bulk, unlabeled, white tablets identified "Lemmon 714." These tablets, as identified, resemble the class II controlled substance manufactured by Lemmon Company under the brand name of Quaalude (300 mg. tablets of methaqualone). The seized tablets contained, upon analysis, either diphenhydramine (an antihistamine) or no drug substance at all. These drugs were found by the Florida Game and Fresh Water Commission near an unmarked airplane in Collier County. The Commission and the Drug Enforcement Administration (DEA), having no jurisdiction, requested the Food and Drug Administration (FDA) to assist in assuring that the products were not distributed. The origin of the tablets has not been determined.

Question #1b.

What additional regulatory actions is FDA contemplating at this time?

Answer

Following the seizures at the known manufacturers, the FDA continued its investigation to determine if the firms involved in the initial seizures are adjusting or are maintaining their roles in the production and distribution of the look-alike products. Additionally, the Agency has undertaken investigations of a number of distributors to determine the effect the seizures may have had on the supply of counterfeits and to what extent there continues to be the marketing of OTC imitation products as controlled substances. Appropriate regulatory action will be considered against distributors if indicated.

Question #1c.

Have criminal proceedings been instituted against any of the nine manufacturers involved in the seizure action? If not, please indicate whether FDA intends to bring any criminal actions as a result of your look-alike investigation.

Answer

Criminal proceedings have not been instituted against any of the nine manufacturers. The enforcement strategy we used was to provide immediate impact on the counterfeit sources by identifying and seizing the equipment suitable for use in the manufacturing of the drug products. We are now reviewing the evidence obtained from the investigations to determine whether to proceed with criminal charges.

Question #2a.

Now that more than two months have elapsed since the seizure actions were carried out, what evidence do you have that the seizures have either made, or failed to make, an appreciable impact on the continued manufacture and distribution of look-alike products?

Answer

Since the seizures, the FDA has continued its civil actions against these firms. Three have now entered into consent decrees of permanent injunction, to stop the manufacture and distribution of OTC counterfeit and look-alike drugs. The remaining six firms are in various stages of discovery or settlement. The Agency is also maintaining surveillance over the firms, and we will keep you informed of the results of these activities.

Question #2b.

Is there any evidence that look-alike production has shifted to clandestine or foreign operations? If so, please elaborate.

Answer

Aside from the incident mentioned in question #1a, we have little information that OTC look-alike production has shifted to foreign operations. It had appeared that the airplane involved may have come from outside the United States. One clandestine operation in southern Wisconsin has come to the attention of the Agency. Based on information supplied by informants, that counterfeit drugs were being produced or held on a farm, an investigation was undertaken by authority of a criminal search and seizure warrant. The warrant was served in mid-January and the investigation is still underway. We will keep you advised of any significant regulatory actions that may evolve from this action.

Question #3a.

Wouldn't it be fairly easy for a look-alike manufacturer to circumvent the counterfeit prohibitions of your law by making slight alterations in the appearance of his products? Do you have any evidence that this is happening?

Answer

Yes, the further away in appearance an OTC look-alike drug is from an exact mimicking of the trademarks or other identifying features of the original drug, the more difficult it is for the FDA to support a counterfeit charge. The FDA has encountered some evidence that this trend is occurring.

Question #3b.

In anticipation of such adjustments by look-alike manfacturers, what other authorities are available to you to control look-alike drugs? In this connection, how does the definition of a counterfeit drug differ from an imitation drug under the Federal Food, Drug and Cosmetic Act? Is your authority with respect to imitation drugs applicable to the look-alike situation? Would the use of your imitation authority with respect to look-alike drugs create any policy problems, e.g. vis-a-vis generic drugs?

Answer

It is possible that the OTC look-alike could be considered imitation drugs and thus controlled under the imitation drug provision of the Act (21 U.S.C. 352(i)). This section provides that a drug is misbranded if it is an imitation of another drug.

The Act defines a counterfeit drug as follows:

> (2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

The Act does not contain a definition of imitation drug, nor is there a legislative history on the drug imitation provision. At one point in the legislative history of the counterfeit provision there is an implication that Congress considered counterfeit drugs to be a part of a broader class of imitation drugs. (H.R. 2, 89th Congress, 1st Session, 8 (1965): H.R. 130, 89th Congress, 1st Session, 4 (1965)).

There may be problems using the imitation authority in connection with the OTC look-alike drugs. When at OTC look-alike drug does not resemble a controlled substance drug product closely enough to be considered a counterfeit, it may be difficult to prove what drug is being imitated. Moreover, there is nothing in the Federal Food, Drug, and Cosmetic Act that directly prohibits trade dress (size, color, and shape) mimicking. In fact, frequently drug products containing both identical and different active ingredients appear visually similar. In particular, generic drug products often use a trade dress similar or identical to the pioneer drug product. Whether such mimicking violates the Lanham Act is currently before the Supreme Court. Oral argument is scheduled on this for February 22, 1981.

Question #3c.

Do you believe your current authorities are adequate to control look-alike drugs. If not, please explain what additional authorities are needed?

Answer

It is unclear whether FDA's current authorities under the Federal Food, Drug, and Cosmetic Act are adequate to control trafficking in look-alike drugs. Until there is a court ruling, it is uncertain whether actual instances of passing off are necessary to support a counterfeit or imitation charge. At point of manufacture, the OTC look-alike drugs are in properly labeled containers and are correctly identified as to active ingredients. Passing off, when it occurs, happens in the schoolyard and the street and not at the manufacturing or distributing levels. Unlike local police and the Drug Enforcement Administration, FDA is not equipped to operate with undercover agents on the street and schoolyards.

Question #4

In your inspections of look-alike manufacturers, did you uncover any evidence of adulteration or misbranding of look-alike products? If so, what specific violations did you find? What actions have you taken as a result of your findings?

Answer

The entire focus of this investigation so far has been based on the counterfeit provisions of the Act. While good manufacturing practices (GMP) violations were noted during the inspections of some OTC look-alike manufacturers, seizures under the counterfeit provisions were deemed sufficient and most appropriate to remove these products from the marketplace. Also, for the most part, the containers of these OTC look-alike products met all basic labeling requirements. This further supported the Agency's decision to take all actions based on the counterfeit provisions of the Act.

Question #5a, #5b, and #5c.

Are the combinations of ingredients frequently found in look-alike drugs (e.g. caffeine, phenylpropanolamine and ephedrine) rational combinations? In other words, do such combinations serve any recognized medical purpose? Are they safe and effective?

Why aren't the manufacturers of look-alike drugs required to obtain approval for these new combinations under the new drug provisions of the Federal Food, Drug and Cosmetic Act?

What problems would FDA encounter in attempting to use the new drug provisions of the Act against look-alikes?

Answer

The marketing status of these drug ingredients have been the subject of two major drug product review programs undertaken by FDA over the past 15 years. These are the Drug Efficacy Study Implementation (DESI) program and the OTC Drug Review.

The Agency instituted the OTC Drug Review in order to evaluate the safety and effectiveness of all OTC drugs then on the market, on a class-by-class basis (see attached copy of the May 11, 1972, Federal Register). As we were aware that many of the OTC drugs then on the market had not been cleared through the new drug procedures of the Federal Food, Drug, and Cosmetic Act. The OTC Drug Review is designed to categorize all OTC preparations into basic categories. From the review there will be published monographs for each basic category to establish conditions under which the OTC drugs will be generally recognized as safe and effective and not misbranded. Each OTC product will have to either meet the standards of an appropriate monograph, which may require reformulation and/or relabeling, or seek approval through the new drug procedures of the Act.

The OTC Drug Review is the primary route for determining the safety and effectiveness of OTC ingredients and formulations and the new drug status of the above ingredients when used in OTC drugs that have been deferred to the OTC drug review process. Under the program, over-the-counter preparations containing these ingredients are exempt from filing a new drug application pending publication in the Federal Register of the appropriate final monographs described above.

At the present time various combinations of the three ingredients including combinations of all three ingredients offered as OTC decongestant/stimulants are permitted on the legitimate OTC market pending the outcome of the OTC Drug Review. Phenylpropanolamine is found in numerous OTC cough/cold (as a nasal decongestant) and appetite suppressant products as a single entity or in combination with other ingredients and in prescription (nasal decongestant) cough/cold products. At this time phenylpropanolamine can be marketed as follows:

1. OTC cough/cold products as a nasal decongestant

   a. immediate release up to 50 mg per dose not to exceed a total daily dosage of 200 mg.

   b. timed release up to 75 mg per dose not to exceed a total daily dosage of 150 mg.

2. Prescription cough/cold products

   Phenylpropanolamine, when combined with other ingredients restricted to prescription sale, may only be marketed as a prescription drug. Virtually all prescription drugs containing phenylpropanolamine are offered for cough/cold indications within the above referenced dosage.

3. OTC appetite suppressant products

   a. immediate release up to 37.5 mg per dose not to exceed a total daily dosage of 75 mg.

   b. timed release up to 75 mg per dose not to exceed a total daily dosage of 75 mg.

Ephedrine sulfate is available OTC and by prescription as a single entity or in combination for use in cough/cold/allergy products as a nasal decongestant or for use in asthma. Ephedrine sulfate is available OTC in an immediate release dosage of up to 25 mg per dose not to exceed a total daily dosage of 150 mg. Ephedrine sulfate in excess of 25 mg per dose and not more than 50 mg per dose may be sold only by prescription.

Caffeine is also found in numerous cough/cold, internal analgesic, appetite suppressant, and other drug products both as OTC and prescription drugs. For example, caffeine is found OTC in stimulant products as a single entity in an immediate release dosage of up to 250 mg. It is also found in OTC appetite suppressant products in immediate release dosage of up to 200 mg in combination with phenylpropanolamine and in OTC internal analgesics and OTC cough/cold products as an adjuvant usually in immediate release dosage of up to 32 mg per dose. Caffeine is used in combination with prescription ingredients for its various pharmacological actions; e.g., nervous system stimulant, diuretic, and its action on the cardiovascular system. However, as we discussed above, its presence in these OTC/prescription products does not connote prior approval in every instance.

Question #6a.

In light of the widespread abuse of look-alike products and the health risks that look-alike drugs present (as well as the concerns that have been raised recently about the safety of PPA in certain OTC diet products) should look-alike components such as ephedrine, PPA, and possible others be scheduled under the Controlled Substances Act? Should such substances be available only by prescription?

Answer

Although there have been widespread reports of abuse of OTC weight reducing preparations formulated to look like controlled substances, the products are composed of drugs such as ephedrine, phenylpropanolamine (PPA), and caffeine, which otherwise are available over-the-counter to the general public. At this time, there is little evidence that the substances which are available over the counter have been diverted or abused. PPA and ephedrine are contained in numerous products for cough and colds, and for sinus problems. Such products as Allerest, Contac, Coricidin, Vicks 44-D decongestant cough mixture, 4-Way Nasal Spray, Novahistine, Sine-Aid, Sine-Off, Sinutab and St. Joseph Cold Tablets for Children, all contain PPA, and there is currently no evidence of their diversion or abuse. Furthermore, control of these substances would not prevent new products from being manufactured which would appear identical with controlled drugs but would contain other currently available OTC substances. The number of substances which can be used to prepare OTC look-alike drugs are too numerous to attempt to control them by scheduling under the Controlled Substances Act. However, the Agency will continue to monitor the use of these drugs and their potential for abuse.

Prescription status for OTC products is always a possibility. OTC drug products require the user to make a self-diagnosis and a self-treatment with the product. Ephedrine, PPA and caffeine have been used in weight-reducing pills in cough and cold preparations, and in sinus preparations for self-treatment. Despite the large volume of sales and wide use of these products, there is little data to estimate the extent of adverse reactions, and what data are available suggests little cause for alarm. Placing these substances under prescription would remove hundreds of products from the OTC market which are believed to be useful for their indication. Placing these drug substances under prescription status is always a possibility, however, if other methods of control are unsuccessful.

Question #6b.

What is the status of the FDA's major OTC review process with respect to PPA and ephedrine? What conclusions, whether preliminary or final, have been reached concerning those two drugs? If monographs on those drugs have been prepared, either in draft or final, will you please provide the Committee with copies?

Answer

Both phenylpropanolamine (PPA) and ephedrine have been reviewed by the OTC drug advisory panels which are part of the review process. The Agency is in the process of formal rulemaking and no final actions have been taken at this time. In the Federal Register of September 9, 1976 (copy attached) the cough-cold panel recommended that PPA be included in a monograph as safe and effective for OTC drug use as a nasal decongestant (41 FR 38400). This recommendation was part of an advance notice of proposed rulemaking. The notice of proposed rulemaking (tentative final monograph) is currently being drafted. In another rulemaking, the OTC miscellaneous internal panel recommended that PPA be included in a monograph as safe and effective for use as an OTC weight control drug product. This document is currently under review in the Department of Health and Human Services.

Ephedrine was classified by the cough-cold panel as safe and effective as a nasal decongestant and as a bronchodilator (see pages 38397 and 38370 of attached Federal Register of September 9, 1976.) These recommendations were also part of an advance notice of proposed rulemaking.

Questions #6c.

As a result of the look-alike phenomenon and other evidence of potential serious health risks from PPA especially, what steps, if any, has FDA taken to review independently the safety and efficacy of ingredients commonly used in look-alikes? What conclusions have you reached as the result of any such review?

Answer

The issue of PPA and the desire to place it in context with other analagous drugs used in the look-alikes has stimulated FDA to look at the general area of commonly used adrenergic drugs which are similar to PPA. Most look-alikes appear to contain either singly or in combination, PPA, caffeine, and ephedrine or pseudoephedrine. All of these drugs that act as stimulants are currently under study in the Bureau of Drugs.

The adrenergic stimulants, PPA, ephedrine, pseudoephedrine and phenylephrine, all share similar pharmacologic properties but are sometimes used in slightly different settings. Caffeine, which is pharmacologically a methylxanthine, and thus somewhat different than the adrenergic agents, will also be evaluated to the best of our ability. Some of the cases in the study suggest its hazard if taken in excessive doses.

The study of these drug components is in progress and monographs on each of the drugs will be made available to the Committee when completed. The monograph for OTC stimulants should be available in a few weeks.

Question #7

At the hearing, you indicated that penalties under the Federal Food. Drug and Cosmetic Act are outdated and that legislation to increase these penalties has been requested in past years.

Question #7a, 7b and 7c

Please explain in greater detail what this legislation would have done?

Has any such legislation been submitted to the Congress this year?

If so, has it been introduced? If not, do you plan to seek such legislation in this Congress?

Answer

Since 1972, the proposal to increase criminal fines has been a part of three Omnibus bills to amend the Federal Food, Drug, and Cosmetic Act S. 3012 (93rd), H.R. 14256 (94th), and H.R. 7035 (96th).

Both Administration drug reform bills, S. 2755 (95th) and S. 1045 (96th), similarly provided for increased criminal fines for certain violations of the Drug Regulation Reform Act.

The above-mentioned proposals would have amended the Federal Food, Drug, and Cosmetic Act to increase fines for violations of the Act to $10,000 (first offense) and $25,000 (second offense). Current law provides a maximum fine be imposed for a violation of the Act at $1,000 and $10,000 if the violation is a second offense or committed with intent to defraud or mislead. These fines were considered far too low and offered little or no deterrent to potential violators.

Question #8

Since the hearing, what steps has FDA taken with other Federal agencies to establish a formal interagency mechanism to monitor look-alike problems and coordinate Federal efforts against look-alike drugs?

Answer

In cooperation with other Federal agencies, FDA has initiated a formal meeting schedule of approximately every six weeks to coordinate interagency activity in the control of the distribution of these drug products. The other agencies include the Drug Enforcement Administration, the Federal Trade Commission, the U.S. Postal Service, and the Internal Revenue Service.

Question #9

At the hearing, you indicated that FDA does not have the expertise to enforce the Federal Food, Drug and Cosmetic Act with respect to street-level sales of look-alike drugs, even though such sales frequently violate the Act.

Question #9a and #9b.

Since DEA does have such expertise, do you believe it would useful if DEA agents were authorized to make arrests for violations of your Act that they encounter in their enforcement activities under the Controlled Substances Act?

What problems do you foresee in this approach?

Answer

We do not object to providing authority for DEA to make arrests or seizures for street level violations of the Federal Food, Drug, and Cosmetic Act. However, if the intention of the Congress is to give the DEA further authority to properly control the sale of such products, FDA believes it would be more appropriate to amend the Controlled Substances Act to embrace any product sold to represent or substitute for a controlled substance.

(Excerpts from the Federal Register, included as attachments to FDA's responses to questions 5 and 6, have not been reproduced because of their length.)

APPENDIXES

The following appendixes consist of materials submitted for the record by various organizations and persons who did not appear at the hearing.

APPENDIX A

STATE OF DELAWARE
DEPARTMENT OF JUSTICE
820 N. FRENCH STREET
WILMINGTON, DELAWARE 19801

[illegible] McGLEIN
[illegible]

PHONE 302
571-3838

October 21, 1981

The Honorable Leo C. Zeferetti
Chairman
Select Committee on Narcotics
  Abuse and Control
Room H2-234
House Office Building Annex 2
Washington, D.C. 20515

Dear Congressman Zeferetti:

Enclosed herewith is a copy of comments that I would appreciate having inserted in the record of your hearings to be held in Jersey City, New Jersey on October 26, 1981. Unfortunately, I will not be able to attend the conference in person because of previous commitments, but I would appreciate it if the Committee would consider these very real and urgent concerns.

Thank you very much for your consideration in this matter.

Yours very truly,

Richard S. Gebelein
Attorney General

RSG/pdw

Enclosure

82 601 O - 82 - 9

STATE OF DELAWARE
DEPARTMENT OF JUSTICE
820 N. FRENCH STREET
WILMINGTON, DELAWARE 19801

October 26, 1981

STATEMENT OF RICHARD S. GEBELEIN,
ATTORNEY GENERAL OF THE STATE OF DELAWARE,
ON THE SUBJECT OF LOOK-ALIKE DRUGS

Mr. Chairman, I am pleased to be able to present my concerns to you and your Committee with regard to a problem that is rapidly spreading across this nation. That problem is the production and marketing of "look-alike" drugs. These drugs, which usually contain caffeine, ephedrine and phenylpropanalamine are prepared in a form that is identical to or extremely similar to controlled substances, such as amphetamines. These drugs are sold openly in most states and are marketed by sophisticated techniques. They are marketed to young, impressionable teenage and younger youth across this country.

Aside from the dangers which large doses of these drugs cause in and of themselves, they increase the likelihood that young people will become involved in abusing controlled substances. In most cases, the juvenile user is unaware that the drug is a "look-alike", but rather believes that it is

"the real thing". This creates a feeling of confidence in the young user that he can handle large quantities of amphetamines and other dangerous drugs, when in fact, he has never really had any. This confidence, I am sure, leads to many deaths from overdose when the young man or woman finally comes into possession of controlled substances. A large dose of the real thing is taken and the individual's system simply cannot accept it.

While there may be a feeling on the part of some to blame these young men and women and to dismiss the consequences of these overdoses as their own fault, the fact is that companies and individuals are using all of the skills of marketing techniques to inculcate our young people with a desire for and a dependence on drugs. The profits that are made each year from the sale of these drugs are enormous. The motivation for production and sale is greed. The Congress and the state legislatures must act to control this greed to protect our society.

In Delaware, we have passed a "look-alike" drug bill, the first of its kind in the nation. I enclose a copy of that law for the Committee's consideration. Other states have followed Delaware and have also passed legislation to control this problem. I know from recent news articles that the Federal Drug Administration is beginning to act. But the producers and marketers of these drugs are acting faster and sometimes more effectively than the law enforcement agencies. In a recent case in our state, an employee of a sales operation boasted to our undercover officer that the FDA was cracking down, but that they were changing the

format and form of their "legal drugs" to avoid the problems associated with that regulation. The same distributor indicated that although he knew that it was against the law to sell these drugs in the State of Delaware, he would ship them to our undercover agent by United Parcel. He would not, of course, come into the State of Delaware to make the delivery.

I would suggest strongly that the Federal government adopt statutes making it a Federal crime to transport these materials across state lines where the state has prohibited their sale. Thus, Federal law enforcement agencies would be able to assist in the prosecution of large scale distributors who supply local dealers in states such as Delaware.

Dealers of these drugs routinely sell them under the names of the controlled substance that they are supposed to resemble. They take phone orders for quaaludes, percodan, dexedrine, and other dangerous controlled substances. Again, this is an area where Federal law enforcement efforts would likely be most successful.

In Delaware, we have actively enforced our "look-alike" drug bill. We have also achieved a result which is somewhat satisfying in that local dealers have moved from Delaware to Pennsylvania and Maryland. Our intelligence information has indicated to us that many dealers will not deal in the State of Delaware because of our law. Unfortunately, some still do.

I want to commend this Committee on having these public hearings to discuss this very important and crucial issue. I do not believe that the general public is at all aware of the severe danger which these drugs pose to the youth of our nation. In speaking across the State of Delaware about the drug problem and "look-alike" drugs, I have found that most people are unaware that literally millions of these pills are being sold in this country. I strongly urge this Committee to take prompt and strong action to prohibit the sale of these drugs nationwide.

HOUSE OF REPRESENTATIVES

130TH GENERAL ASSEMBLY

HOUSE BILL NO. 909

AS AMENDED BY

HOUSE AMENDMENT NOS. 1 AND 2

AN ACT TO AMEND CHAPTER 47, TITLE 16 OF THE DELAWARE CODE RELATING TO FRAUDULENT DELIVERY OF NON-CONTROLLED SUBSTANCES AND TO CREATE A DEFINITION OF FINISHED PRODUCT

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 47, Title 16 of the Delaware Code by adding a new Section 4752A to read as follows:

"(1) It is unlawful for any person knowingly to deliver or attempt to deliver a non-controlled substance upon either:

(a) The express representation that the substance is a narcotic or non-narcotic controlled substance; or

(b) The express representation that the substance is of such nature or appearance that the recipient of said delivery will be able to distribute said substance as a controlled substance; or

(c) Under circumstances which would lead a reasonable person to believe that the substance was a controlled substance. For the purposes of this section, it is prima facie evidence of such circumstances if any two of the following factors are established.

(i) The non-controlled substance was packaged in a manner normally used for the illegal delivery of controlled substances.

(ii) The delivery or attempted delivery included an exchange of or demand for money or other valuable property as consideration for delivery of the substance, and the amount of such consideration was substantially in excess of the reasonable value of the non-controlled substance.

(iii) The physical appearance of the finished product containing the substance is substantially identical to a specific controlled substance.

(2) In any prosecution for Fraudulent Delivery of a controlled substance, it is no defense that the accused believed the non-controlled substance to actually be a controlled substance.

(3) Fraudulent Delivery of a non-controlled substance is a felony. The punishment upon conviction under this section shall be governed by those provisions of this code dealing with delivery of controlled substances. Specifically, the section prohibiting delivery of the controlled substance, which the defendant represented the non-controlled substance to be, shall govern the punishment in each case. If no express representation was made as to the identity of the controlled substance, the punishment shall be the same as for delivery of a non-narcotic controlled substance. However, the punishment provision of Section 4751(b) shall not apply to this section."

Section 2. Amend Chapter 47, Title 16 of the Delaware Code by adding a new subsection 12(a) to Section 4701 to read as follows:

"12(a) Finished Product - Any material compound mixture or preparation which contains any quantity of a controlled or non-controlled substance."

APPENDIX B

TYRONE C. FAHNER
ATTORNEY GENERAL
STATE OF ILLINOIS
100 NORTH LA SALLE STREET
CHICAGO 60601

TELEPHONE
793-3000

October 22, 1981

The Honorable Leo C. Zeferetti
Chairman
U.S. House Select Committee on
Narcotics Abuse and Control
Room H2-234, House Office Building
Annex 2
Washington, D.C. 20515

Dear Congressman Zeferetti:

Thank you for your invitation to address this committee on a subject which calls for urgent federal action.

We are faced with a serious drug problem in America that many of us didn't even know existed a few years ago. I would even venture to say that the spread of "look alike" drugs is the fastest growing drug problem in the country, and perhaps the most deadly.

We know of six deaths attributable to the use and abuse of "look alike" drugs over the past nine months here in Illinois. I say "We know of six deaths," because some parts of the State - including the City of Chicago - do not keep records on drug overdose deaths that would differentiate between deaths due to controlled and non-controlled substances.

There have been more actual deaths linked to "look alikes" than real amphetamines in Illinois. And, this is a figure I find astounding. We estimate that earlier this year, 15 times more "look alikes" were being manufactured in this country than amphetamines. Before June, 1.7 billion doses of "look alikes" were produced each year. That means 8 "look alike" tablets or capsules for every man, women and child in America.

Those are frightening statistics. They are even more so when you consider that these drugs are legal, they are manufactured without any quality control, and they are being pushed on very young children as "safe and profitable stimulants."

How dangerous are "look alikes?" Well, the last person we know to have died in Illinois in relation to the drugs was a State Fair worker. On August 4, the young lady took just a couple of capsules - and she's dead.

Many people in law enforcement, believed nothing could be done at the state level, to restrict these drugs. I received complaints from drug agents, local police and sheriffs, parents and school administrators. I was sympathetic, but without an apparent remedy because no state or federal criminal law applied, there seemed little we could do. Then I was given a copy of a pamphlet being distributed on desks at a high school in Springfield. The pamphlet said "Why pay more to an unlicensed street dealer?" The inside offered an assortment of pil's, and an assurance that the "look alikes" are "legal, safe, effective and pro_itable stimulants." You could buy them - mail order - by the tens of thousands. Other companies even offered free samples by mail.

We decided something must be done. In May, we took our first action. We filed suit against R.S.L. Pharmacal of Maryland and three of its owners. That company is now out of business. We alleged violations of the Illinois Consumer Fraud & Deceptive Business Practices Act, Illinois Consumer Fraud & Deceptive Trade Practices Act and the common law of nuisance.

Over the past five months, the number of manufacturers and distributors we've sued has grown to 39 in 14 states.

About half of the firms we've sued have voluntarily stopped doing business in Illinois. And, "look alike" manufacturers admit the flow of the drugs has dropped from about 30 million capsules and tablets a week to 5 million.

But, we have no illusions about our success. Some companies we have sued and closed have popped up again under a new name. And just because we stop a "look alike" distributor in Illinois, doesn't mean we've solved the national problem - perhaps in your state.

I have drafted legislation in the Illinois General Assembly to ban the manufacture and distribution of "look alikes." Violation would be a felony. We are now working with Congressmen and the federal government on national legislation. That will take time, and more time than we have to save some lives. Each state should take action.

The people who peddle "look alikes" are the same type of sleazy people who will try anything to promote the drug culture to children just to make a buck. I'm convinced that if we take the profit out of this business, it will dry up.

Each year about this time, we read in the newspaper about a child who is seriously hurt because some sick person puts a razor blade in an apple or drugs in candy for Haloween trick or treaters. They deceive children by putting something that hurts them into something that appears safe. We think "What type of person would do that to a child?", and we prosecute them. The people who push "look alike" drugs on kids are no better.

Warmest personal regards,

ATTORNEY GENERAL

82nd GENERAL ASSEMBLY
State of Illinois

1981 and 1982

INTRODUCED _____, BY

Watson - Maitland

SYNOPSIS: (Ch. 56 1/2, par. 1404)

Amends the Controlled Substances Act to make the distribution, or possession with intent to distribute, of a noncontrolled substance, by a person who reasonably should know that the substance may be used or distributed as a controlled substance, a Class 3 felony with fine up to $15,000.

LRB8205221EGjs

A BILL FOR

AN ACT to amend Section 404 of the "Illinois Controlled Substances Act", approved August 16, 1971, as amended.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Section 404 of the "Illinois Controlled Substances Act", approved August 16, 1971, as amended, is amended to read as follows:

(Ch. 56 1/2, par. 1404)

Sec. 404. (a) For the purposes of this Section:

(1) "Noncontrolled substance" means any substance other than a controlled substance as defined in this Act.

(2) "Distribute" means the actual, constructive or attempted transfer, exchange or delivery of a noncontrolled substance from one person to another with or without remuneration, whether or not there exists an agency relationship. However, "distribute" does not include what would be dispensing, as defined in this Act, but for the fact that the substance involved is a noncontrolled rather than a controlled substance.

(b) Except as authorized by this Act, it is unlawful for any person knowingly to distribute deliver or possess with intent to distribute deliver any noncontrolled substance which he represents to be a controlled substance.

(c) It is unlawful for any person to distribute or possess with intent to distribute any noncontrolled substance under circumstances where such person reasonably should know that the noncontrolled substance may be used or distributed as a controlled substance.

(d) For the purpose of determining whether a person reasonably should know that a noncontrolled substance may be used or distributed as a controlled substance, the court or trier of fact shall include in its consideration one or more of the following:

(1) whether the noncontrolled substance was packaged in a manner normally used for the illegal distribution of controlled substances;

(2) whether the distribution or attempted distribution included an exchange of or demand for money or other property as consideration, and whether the amount of the consideration was substantially greater than the reasonable value of the uncontrolled substance;

(3) whether the physical appearance of the noncontrolled substance is substantially similar to that of a controlled substance with regard to shape, color, size, markings or other identifying physical characteristics of the substance, and whether the similarity of the noncontrolled substance to a controlled substance creates a reasonable likelihood of confusion or misidentification between the noncontrolled substance and the controlled substance to which it bears a resemblance, regardless of any statements of the noncontrolled nature of the substance which may appear on the original packaging or in the promotional or other materials associated with the noncontrolled substance.

(e) In any prosecution brought under this Section, it is not a defense to a violation of this Section that the defendant believed the noncontrolled substance to actually be a controlled substance.

(f) Any person who violates this Section is guilty of a Class 3 felony. The fine for violation of this Section shall not be more than $15,000.

APPENDIX C

POSITION PAPER ON LOOK-ALIKE DRUGS

PRESENTED BY NEW JERSEY STATE POLICE

OCTOBER 1981

The New Jersey State Police has recognized and acknowledged the severity of drug abuse in our State and the physical and psychological debilitating effects which accompany it. Commensurate with the enforcement efforts of our Narcotic Bureau, we further realize that rigorous enforcement is our most effective tool in combatting this problem.

Intelligence sources have provided us with the knowledge that "look-alike" products are easily available in New Jersey, that both legitimate and illegitimate sources are within our borders and that "look-alike" drugs have emerged as a serious problem. They are marketed legitimately as sleeping aids, body stimulants, etc. These popular non-controlled substances contain caffeine, which may induce cardiac irregularities, ephedrine, which may cause toxic effects, and phenylpropanolamine (PPA) which may cause nervousness, nausea, palpitations and excessive rises in blood pressure. Complaints from all levels of our society have indicated that the indiscriminate advertisement and distribution of "look-alike" drugs are directed toward our youth. Brochures depicting the various tablets and capsules, most of which are similar in appearance to legitimately manufactured drugs often chosen by controlled dangerous drug (CDS) abusers, are easily available via mail order or through street distributors.

Because the look-alike drugs contain no controlled substances, the sale of such drugs, either by a distributor or a street peddler is not prohibited by law. This is cause for major concern by our citizenry, who are frightfully alarmed over enforcement officials' inability to deal with the problem.

The New Jersey State Police concurs that restrictions must be formalized that would curtail the availability of the look-alike drugs, if for no other reason than to shield our youth from introduction into a drug abuse environment.''

The State of Delaware has already enacted a law that makes it illegal to deliver or attempt to deliver a non-controlled substance (look-alike drugs). The law specifically concentrates on the distribution of non-controlled substances, if the express or implied representation is that the substance is a controlled dangerous substance, or that the substance is of such nature or appearance that the recipient of the delivery will be able to distribute the substance as a controlled dangerous substance. This law provides Delaware enforcement officials with the power to combat the "look-alike" drug entrepreneurs.

Federal legislation similar to that of Delaware would certainly enhance the effectiveness of Federal law enforcement and encourage the States to follow suit. Prohibitive legislation would be particularly advantageous in the area of undercover drug investigations where agents purchase specimens only to have the case frustratingly terminated subsequent to the analysis of suspect materials as being "look-alikes".

We favor the enactment of legislation to combat the distribution of look-alike drugs. The law should contain wording prohibiting the sale and distribution of non-controlled substances which are packaged and sold in a manner generally associated with illegal drugs, e.g., heroin, cocaine, stimulants and depressants. In addition, it is recommended that Federal legislation contain sections that would prevent the advertisement of look-alike drugs and the promotion sale and distribution of non-controlled drugs through the U.S. mail.

Thank you for inviting the New Jersey State Police to provide an opinion on this subject. It is committees such as yours that sort out the problems in our society and provide meaningful data which suggests methods for attacking them.

APPENDIX D

New Jersey
Narcotic Enforcement Officers Association

October 21, 1981

P. O. BOX 1720
NEWARK, N. J. 07101

STATEMENT OF WALTER R. BETYEMAN,
PRESIDENT, NEW JERSEY NARCOTIC ENFORCEMENT OFFICERS ASSOCIATION
ON
LOOK-ALIKE DRUGS

The New Jersey Narcotic Enforcement Officers Association is comprised of thirteen hundred persons involved in federal, state, county, and municipal law enforcement, and comprised also of educators, doctors, probation officers, attorneys, pharmacists, and persons from private industry, all of who are concerned with effective drug abuse law enforcement through the administration of existing laws and enactment of legislation.

The recent past has seen the proliferation of a new phenomenon in the drug culture - the "look-a-like" drug. Throughout the State, and indeed, nationwide, unscrupulous individuals are peddling substances which they represent as being CDS, when in fact such substances are not. Invariably, the "look-a-likes" consist primarily of caffein with small additional quantities of common over-the-counter stimulants, such as phenylpropanolamine hydrochloride and ephedrine sulfate.

The trafficking in these "look-a-likes", so called because of their physical resemblance to such drugs as amphetamines and phendimetrazine has become big business. Manufacturers and wholesalers advertise in national publications, such as Cosmopolitan Magazine, where the capsules, billed as "stimulants" and "diet pills", are offered for sale. The pervasive nature of the problem is further underscored by the fact that these products are also advertised in college newspapers, and daily and weekly periodicals. In fact, at a recent concert at the Meadowlands Arena, flyers extolling these items were placed on the windshields of vehicles in the parking lots.

The major enforcement problem, insofar as "look-a-like" drugs are concerned, arises from the fact that larcenous individuals, out to make

a fast buck, purchase the capsules in bulk, and sell them on the street individually or in small quantities. That a fast buck is to be made cannot be denied - for what is bought at a price of $15 - $20 per hundred, or $75 per thousand, can be sold on the street for $1 to $1.50 per pill.

Unfortunately, it is the youth of our society who are most inclined to use and experiment with drugs, and thus it is they who most often fall prey to the purveyors of the "look-a-likes". Furthermore, the ingestion of these caffein pills is not without certain dangers. Unsuspecting youngsters, buying and ingesting what they believe to be amphetamines, do not experience the sensation they have come to expect. This results in the ingestion of more and more caffein capsules, which not only compounds psychological problems already present, but can cause a rapid, irregular heartbeat. Additionally, future problems arise when a youngster, having experienced no effect from the "look-a-likes" in the past, and thus mistaking his own tolerance, overdoses on real amphetamines.

There are those who will say "it serves them right" when speaking of those who are defrauded by the sellers of the "look-a-likes". But this approach ignores the fact that the youth, the unsuspecting, the unfortunate are being "ripped off". Such an attitude certainly does not contribute to the solution of our epidemic drug problem. It merely serves to underscore the frightening phenomenon that our kids will ingest substances, either alone or in combination, without actually knowing what those substances are, or what their effects may be.

At the present time there is no effective statute in this state with which to prosecute the street distributors of the "look-a-like" drugs. The unsuspecting customer, including on many occasions the undercover police officer, has no recourse by which he can recover his money. Society has no recourse by which it can deter such fraudulent practices. Thus, the time is ripe to enact legislation which will provide a cure. The New Jersey Narcotics Enforcement Officer's Association wholeheartedly supports legislation, similar to that pending in six other states, which would make it a criminal offense to sell, any product similar in appearance to a CDS by means of false representations as to its character.

We, as parents, educators, and members of the law enforcement community owe a duty to society in general, and our youth in particular, to make every effort possible to expose and curtail those culpable of preying upon the unsuspecting and unfortunate, and to educate the public in this area, as well as all areas, of drug abuse. On behalf of the NJNEOA, I commend this Committee for its efforts towards achieving those goals.

Very truly yours,

Investigator Walter R. Betyeman
President

WRB:cz
enclosures

APPENDIX E

Statement by

Warner-Lambert Company

to the

House Select Committee on Narcotics Abuse and Control

Jersey City, New Jersey

October 26, 1981

Mr. Chairman and Members of the Committee:

Warner-Lambert Company is pleased to have the opportunity to provide this written statement to the Committee on behalf of its Capsugel Division, which supplies empty gelatin capsules to the pharmaceutical industry.

Capsugel and its predecessors have achieved considerable expertise in the production of gelatin capsules for medical and therapeutic purposes. They have been making capsules for nearly 100 years, having begun in 1888. Initially, capsules were made for the company's own use. However, for more than 60 years the company has marketed its empty hard gelatin capsules on a worldwide basis to other pharmaceutical companies which then fill them with their own products. Capsules for the United States market are produced at our Greenwood, South Carolina, manufacturing facilities.

Your staff indicated you would like us to address the question of the sale of non-prescription drugs as substitutes for controlled substances from the perspective of the manufacturer of the empty capsules. At the outset we want to state that Capsugel, as a major supplier to ethical pharmaceutical manufacturers, has

viewed, and continues to view, this practice as a matter of serious public concern. We have no interest in producing components of a product which is ultimately used for improper or illegal purposes. We are pleased that the committee is taking an active interest in helping industry, regulatory agencies, and law enforcement officials to solve the problem.

We have been particularly focusing on this problem since the spring of 1980 as a result of trade press articles and feedback from our sales representatives and professional staff. Before describing the steps that we have taken in an attempt to curtail the supply of capsules to those involved in this activity and then suggesting ways that government and industry can work together to attempt to halt the proliferation and sale of controlled drug "look-alikes", we believe it pertinent to set forth the practical problems faced by industry, regulatory agencies and law enforcement officials in ascertaining the extent of the problem and solutions to it.

First, capsules are manufactured in literally thousands of color combinations and sizes. The tops and bottoms of the capsules may be of different colors or shades and one color top can be combined with any other color bottom. Secondly, the typical capsule filling equipment can take any capsule top and fit it with any capsule bottom to produce a desired combination. For example, the top from a black top and yellow bottom capsule can be exchanged with the top from a yellow top and black bottom capsule to produce black-black and a yellow-yellow capsules which

87-601 O - 82 - 10

are the combinations which we understand to have been widely used in the activity under investigation. Thirdly, there are an unlimited number of logos or identifying marks which can be placed on the products.

Another practical problem faced by industry, regulatory agencies and law enforcement authorities alike is the fact that a small number of capsule filling drug manufacturers can supply legitimately labeled products to a large number of customers. Labels can then be altered or false representations made about the capsule contents to purchasers who use the products or resell them to other parties. The current Federal Food Drug & Cosmetic Act and the Controlled Substance Act do not appear to give law enforcement and regulatory authorities an adequate means to control the abuses which are the subject of the Committee's investigation. Additionally, capsule manufacturers are in the disturbing position, if they refuse to sell product, of potentially being challenged with claims of illegal restraint of trade and improper interference with state drug substitution laws.

We will now briefly describe the series of unilateral actions which Capsugel took to try to stem the use of its capsules in the manner under discussion.

<u>First, we stopped imprinting certain capsules which were reported as being used in the practices under consideration</u>.

It is the practice among pharmaceutical companies to have certain identifying marks, such as logos or numbers, printed on

empty capsules for ethical use. Printed capsules assist the physicians, emergency room personnel, pharmacists and nurses to more quickly identify the products than color-coding alone. We stopped imprinting certain capsules because it was reported that identifying marks on capsules supplied to the OTC market resembled those of certain prescription drugs, such as the amphetamines. Thus, we initially stopped any imprinting on number three size, black-black and yellow-yellow capsules which we understood to be the size and colors involved in the "look-alike" problem.

Secondly, we stopped accepting orders for capsules of the type and color which reportedly were being abused.

As we continued to monitor the situation and to read about the problem in the trade media, it became apparent that at least some contract capsule fillers had found other means of getting the capsules imprinted. Evidently these individuals found third parties to print identifying marks on the capsules or they acquired printing equipment themselves.

For this reason we unilaterally stopped accepting any further orders for the number three black-black and number three yellow-yellow capsules.

Thirdly, we asked customers to verify for us how they were using such capsules.

Upon learning that additional color combinations and sizes might be involved, we sent a letter to customers advising them of restrictions which we were placing on sales of certain color combinations

and sizes. The letter asked for verification that customers' products in these capsules were being distributed in accordance with applicable local, state and federal laws. It further asked that complete labeling, including package inserts, if applicable, be submitted to Capsugel.

The letter said that, after receipt of the material, a determination would be made whether the finished product was a legitimate generic, for which capsules would continue to be supplied, or a "look-alike" substitute for a controlled substance. Orders for these capsules, consistent with the previously adopted policy, would not be accepted. This was a voluntary good faith effort on Capsugel's part and at the time we recognized that we would lose some rapport with legitimate customers who resented any implication of impropriety on their part. Nevertheless, we did it and we are prepared to take other steps of a similar nature if necessary and appropriate.

At this juncture, we believe that we have taken appropriate action to curtail the supply of capsules in the size and color combinations reportedly favored as controlled drug "look-alikes". We have stopped imprinting; we stopped taking orders; and we require proof of use. As a private corporation, we, of course, lack the authority to inspect, license or monitor the production of our customers. Any further supportive action on our part we believe needs guidance from the law enforcement and regulatory authorities of the federal government.

Now, let us suggest how government can help.

From our perspective, we believe the solution to the controlled drug "look-alike" problem requires new legislation at the federal and state level that would provide law enforcement with the mechanisms to deal with the problems.

As we previously explained to the Committee, Warner-Lambert feels current federal legislation, specifically the Federal Food Drug and Cosmetic Act and/or the Controlled Substances Act should be amended in such a manner that will enable law enforcement authorities to take more prompt action against individuals knowingly trafficking in controlled drug "look-alikes."

In addition, we believe the Committee could suggest model legislation that could be supplied to the states which would enable local law enforcement officers to effectively act on the problem. This model legislation could take the substantive form of recent changes made in certain state laws, such as those made in Maryland and Wisconsin where the promotion of products not in accordance with appropriate labeling regulations is considered an act of misbranding and subjects the product to seizure. Persons knowingly involved in such actions would then be liable for criminal action. However, we urge the Committee to suggest that the amendments to the Act(s) make it clear that knowingly willful acts are the only offenses chargeable in regard to "look-alike" violations. We are of the opinion that this is required due to the fact that unknowing involvement in the production or distribution of controlled drug "look-alikes" can easily occur.

This is especially true for capsule manufacturers in view of the large number of generic producers who buy their empty capsules and then fill them with product. It would also be extremely helpful if the new legislation could provide that a capsule manufacturer could immediately discontinue sales to a suspected violator on notification or request of federal law enforcement agencies or state attorneys general. This would alleviate concerns of potential antitrust or unfair competition legal actions.

We also believe there is need for more awareness of the problem. Obviously, the more the public is aware of the dangers that controlled drug "look-alikes" present, the less likely they are to be used. As a result, we encourage a broad educational effort, especially aimed at the young, to bring to their attention the dangers inherent in controlled drug "look-alikes." While it is difficult for a single company to have significant impact on the ultimate consumers of the products, we would certainly be prepared to cooperate in any type of reasonable educational program to help alleviate the problem.

Again, we would like to say that we are pleased that the Committee is looking into this problem. We appreciate having had the opportunity to present our views to the Committee and we look forward to your recommended action to control this serious problem.

Thank you.

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APPENDIX F

(17) 4

STATEMENT REGARDING THE HEALTH EFFECTS OF

"LOOK-ALIKE" STIMULANTS

By Barry M. Diskant, M.D.

I HAVE BEEN ASKED TO DISCUSS THE HEALTH EFFECTS OF "LOOK-ALIKE" DRUGS BY THE HOUSE SELECT COMMITTEE ON NARCOTIC'S ABUSE AND CONTROL. THE FOLLOWING IS A STATEMENT OF MY VIEWS ABOUT THIS SUBJECT.

MY FIELD OF EXPERTISE IS EMERGENCY MEDICINE, WHICH I PRACTICE AT ST. JOSEPH HOSPITAL IN ALBUQUERQUE, NEW MEXICO. IN THE PAST YEAR THERE HAS BEEN A DRAMATIC INCREASE IN THE AVAILABILITY AND USAGE OF "LOOK-ALIKE" DRUGS IN ALBUQUERQUE, PARALELLING A TREND WHICH SEEMS TO BE OCCURRING ALL OVER THE UNITED STATES. IN OUR EMERGENCY ROOM, WHICH IS ONE OF FIVE IN ALBUQUERQUE, WE HAVE SEEN AT LEAST A DOZEN TOXIC REACTIONS TO "LOOK-ALIKE" STIMULANTS, INCLUDING TWO DEATHS. SINCE MY EXPERIENCE HAS BEEN ONLY IN THE TREATMENT OF "LOOK-ALIKE" STIMULANTS, I WILL CONFINE MY REMARKS TO THIS CATEGORY OF "LOOK-ALIKES". IT SHOULD BE NOTED, HOWEVER, THAT "LOOK-ALIKE" SEDATIVES ARE ALSO AVAILABLE.

"LOOK-ALIKE" STIMULANTS, OR "PIC-ME-UPS", AS THEY ARE SOMETIMES REFERRED TO, ARE MADE TO CLOSELY RESEMBLE PRESCRIPTION AMPHETAMINES. MOST OF THESE "LEGAL STIMULANTS" CONTAIN THE FOLLOWING THREE INGREDIENTS, IN DIFFERING AMOUNTS AND PROPORTIONS: CAFFEINE, WHICH IS CONTAINED IN COFFEE, TEA, AND CARBONATED BEVERAGES; EPHEDRINE A KNOWN VASOPRESSOR (I.E. A DRUG WHICH INCREASES BLOOD PRESSURE), AND COMMONLY USED DECONGESTANT AND ANTI-ASTHMA DRUG, AND PHENYLPROPANOLAMINE, WHICH I SHALL REFER TO AS PPA. PPA IS CONTAINED IN A WIDE VARIETY OF OVER-THE-COUNTER AND PRESCRIPTION MEDICATIONS, AND IS USED PRIMARILY AS AN ANOREXIANT (A DRUG TO SUPPRESS APPETITE) AND AS A NASAL DECONGESTANT. IT HAS BEEN COMMERCIALLY AVAILABLE FOR OVER TWENTY (20) YEARS, AND I DOUBT THAT ANY MEMBER OF THE COMMITTEE HAS NOT, AT ONE TIME OR ANOTHER, INGESTED PPA. IT IS FOUND IN COMMONLY USED COLD PREPARATIONS SUCH AS CONTACT ^{R}, COMTREX ^{R}, DRISTAN ^{R}, SINE-AID ^{R}, VICKS FORMULA 44D COUGH SYRUP ^{R}, AND NUMEROUS OTHERS. PLEASE REFER TO APPENDIX A AND APPENDIX B FOR A LISTING OF OVER-THE-COUNTER AND PRESCRIPTION DRUGS CONTAINING PPA.

IN CONSIDERING THE HEALTH EFFECTS OF "LOOK-ALIKE" STIMULANTS, IT MUST BE BORNE IN MIND THAT ALL THREE INGREDIENTS HAVE STIMULANT PROPERTIES

OF THEIR OWN. THERE HAS BEEN LITTLE OR NO RESEARCH STUDYING THE INTERACTION OF THESE THREE DRUGS. ANYONE FAMILIAR WITH BASIC PHARMACOLOGIC PRINCIPLES IS AWARE THAT DRUGS WITH SIMILAR EFFECTS CAN HAVE SYNERGISTIC EFFECTS; I.E. EACH MULTIPLIES THE EFFECTS OF THE OTHER. I FEEL THAT THERE IS GOOD REASON TO BELIEVE THAT SYNERGISM OCCURS WITH "LEGAL STIMULANT" USAGE.

EACH OF THE INGREDIENTS IN THESE "LOOK-ALIKE" STIMULANTS HAS INDEPENDENT VASOPRESSOR PROPERTIES; THAT IS, THEY CONSTRICT BLOOD VESSELS AND CAUSE AN INCREASE IN BLOOD PRESSURE. A RECENT STUDY REPORTED IN THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (JAMA, FEB. 13, 1981 - VOL. 245, NO. 6) DOCUMENTED AMPHETAMINE-LIKE REACTIONS IN SEVEN (7) PATIENTS AFTER INGESTION OF 50-75 MG. OF PPA. IT IS MY BELIEF THAT THE MAJOR HEALTH HAZARD OF THESE DRUGS IS RELATED TO THEIR ABILITY TO ELEVATE AN INDIVIDUAL'S BLOOD PRESSURE. THERE ARE NUMEROUS REPORTS IN THE MEDICAL LITERATURE DOCUMENTING AMRKED BLOOD PRESSURE EVALUATION AFTER INGESTION OF RELATIVELY SMALL AMOUNTS OF PPA. AN ARTICLE IN THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION AS FAR BACK AS 1965 DOCUMENTS A TRANSIENT HYPERTENSIVE STATE FOLLOWING PPA INGESTION. NUMEROUS ARTICLES AND CASE REPORTS DOCUMENT A RELATIONSHIP BETWEEN TRANSIENT HIGH BLOOD PRESSURE AND PPA USE. CEREBRAL HEMORRHAGES (A TYPE OF STROKE), HYPERTENSIVE CRISIES (A STATE OF ELEVATED BLOOD PRESSURE DURING WHICH THE INDIVIDUAL CAN BE DISORIENTED, AND IS PRONE TO STROKES), AND SEIZURES, OR CONVULSIONS, ALL HAVE BEEN REPEATEDLY DOCUMENTED IN THE MEDICAL LITERATURE. PLEASE SEE APPENDIX C FOR A PARTIAL BIBLIOGRAPHY OF THESE ARTICLES.

IN ORDER TO GIVE THE COMMITTEE A BETTER AND MORE DETAILED PICTURE OF SOME OF THE DANGEROUS EFFECTS OF "LOOK-ALIKE" STIMULANTS, I SHALL PRESENT TWO CASES WHICH WERE SEEN BY ME, AND WHICH CULMINATED IN DEATH.

CASE 1

A TWENTY-FIVE (25) YEAR-OLD PREVIOUSLY HEALTHY MALE WAS BROUGHT TO THE EMERGENCY ROOM APPROXIMATELY FOUR HOURS AFTER INGESTING TWO BLACK "PIC-ME-UP" CAPSULES EACH OF WHICH CONTAINED PPA 30MG, EPHEDRINE 20MG, AND CAFFEINE 200MG. HE WAS FOUND UNCONCIOUS AND UNAROUSABLE BY FRIENDS.

IN THE E.R. HE WAS NOTED TO BE DEEPLY COMATOSE WITH A LARGE HEMORRHAGE BEHIND THE RETINA. BLOOD PRESSURE WAS NOT ELEVATED AT THE TIME OF EXAMINATION. NEUROSURGICAL CONSULTATION WAS OBTAINED, AND A DIAGNOSIS OF INTRA-CEREBRAL HEMORRHAGE (STROKE) WAS MADE. THE PATIENT REMAINED DEEPLY COMATOSE AND EXPIRED APPROXIMATELY TWELVE HOURS LATER. AUTOPSY REVEALED MASSIVE INTRACEREBRAL HEMORRHAGE WITHOUT ANY EVIDENCE OF PREDISPOSING ANEURYSM. TOXICOLOGY DONE UPON ADMISSION REVEALED THE PRESENCE OF EPHEDRINE AND A MINUTE AMOUNT OF ALCOHOL.

CASE 2

A SEVENTEEN (17) YEAR-OLD PREVIOUSLY HEALTHY MALE WAS BROUGHT TO THE EMERGENCY ROOM APPROXIMATELY FIFTEEN HOURS AFTER INGESTING TWO BLACK "PIC-ME-UP" CAPSULES WHICH WERE IDENTICAL IN APPEARANCE AND IN CONTENT TO THOSE DESCRIBED IN CASE 1 (ABOVE). APPROXIMATELY ONE HOUR FOLLOWING INGESTION OF THE DRUGS HE BECAME RESTLESS, ANXIOUS, TREMULOUS, AND IRRITABLE. THIS PERSISTED FOR SIX TO EIGHT HOURS, AT WHICH TIME A DRAMATIC CHANGE IN HIS MENTAL STATUS OCCURRED. HE SUDDENLY BECAME DROWSY, DISORIENTED, AND EXTREMELY LETHARGIC. HE SPOKE NON-SENSICALLY. HE SLEPT FOR PERIODS OF TWO TO THREE HOURS AT A TIME, AND WAS UNAROUSABLE DURING THESE PERIODS.

UPON PRESENTATION TO THE EMERGENCY DEPARTMENT I NOTED A BLOOD PRESSURE OF 120/60 MM HG AND PULSE OF 60/MIN. HE WAS DISORIENTED AND SPOKE INCOHERENTLY. HE COULD NOT ANSWER SIMPLE QUESTIONS SUCH AS HIS NAME, THE DAY OF THE WEEK, HIS PRESENT LOCATION, ETC. HE WAS SOMNOLENT AND IT WAS DIFFICULT TO KEEP HIM AWAKE. TOXICOLOGY DONE AT THE TIME OF ADMISSION REVEALED A URINARY EPHEDRINE LEVEL OF 2UG/ML. NO METHAQUALONE, AMPHETAMINES, OR OPRATES WERE DETECTED IN THE TOXICOLOGIC SCREEN.

HE WAS ADMITTED TO THE INTENSIVE CARE UNIT FOR OBSERVATION. APPROXIMATELY TWELVE (12) HOURS AFTER ADMISSION HE HAD A PROLONGED SEIZURE WHICH WAS FOLLOWED BY CESSATION OF SPONTANEOUS RESPIRATION. HE WAS PUT ON MECHANICAL RESPIRATOR. HIS PUPILS BECAME FIXED AND DILATED. A CT SCAN OF THE BRAIN SHOWED MASSIVE INTRACEREBRAL HEMORRHAGE (A TYPE OF STROKE) ON BOTH SIDES OF THE BRAIN. HE REMAINED DEEPLY COMATOSE. FOUR DAYS LATER, TESTS WERE PERFORMED (EEG AND BAER) WHICH REVEALED BRAIN DEATH. MECHANICAL RESPIRATORY ASSISTANCE WAS DISCONTINUED AFTER DISCUSSION WITH THE FAMILY. HE DIED SHORTLY THEREAFTER. AUTOPSY FINDINGS REVEALED MASSIVE INTRACEREBRAL HEMORRHAGE BILATERALLY. AT AUTOPSY THERE WERE NO -EREBRAL ANEURYSMS WHICH WOULD PREDISPOSE A PERSON TO THIS TYPE OF PROBLEM.

THE CASES OUTLINED ILLUSTRATE THE MOST SEVERE AND DRAMATIC UNTOWARD EFFECTS OF "LEGAL SPEED". THESE OCCURANCES, FORTUNATELY, ARE RELATIVELY RARE. MORE COMMONLY, HOWEVER, OTHER REACTIONS ARE SEEN.

FREQUENTLY USERS HAVE MINOR REACTIONS FOR WHICH THEY DO NOT SEEK MEDICAL ATTENTION. THE SYMPTOMS INCLUDE ANXIETY, TREMULOUSNESS, PARANOIA, RESTLESSNESS, NAUSEA, VOMITING, BLURRED VISION, HEADACHE, INSOMNIA, PALPITATIONS, AND DISORIENTATION. I HAVE SEEN THESE REACTIONS AFTER AS LITTLE AS ONE "LOOK-ALIKE" CAPSULE. AN OVERDOSE IS NOT REQUIRED TO PRODUCE TOXIC REACTIONS. MOST OF THE PATIENTS THAT I HAVE SEEN IN THE EMERGENCY ROOM HAVE HAD MARKEDLY ELEVATED BLOOD PRESSURE, IN THE RANGE, AT TIMES OF 260/160 MM HG. THESE PATIENTS DID NOT TAKE OVERDOSES. THEY WERE TREATED WITH DRUGS TO LOWER THE BLOOD PRESSURE, AND WERE HOSPITALIZED FOR PURPOSES OF OBSERVATION. MARKEDLY ELEVATED BLOOD PRESSURE DOES INCREASE THE CHANCES OF A PERSON HAVING A STROKE. ALTHOUGH NOT ALL PERSONS HAVE THESE HYPERTENSIVE RESPONSES, I KNOW OF NO WAY TO PREDICT WHO WILL AND WHO WON'T.

THE MAJOR HEALTH EFFECTS OF THESE "LOOK-ALIKE" STIMULANTS, THEN, IS THEIR ABILITY TO PRODUCE, IN SOME INDIVIDUALS, HYPERTENSIVE STATES WHICH CAN PREDISPOSE THAT PERSON TO HAVING A STROKE.

OTHER HEALTH EFFECTS EXIST AS WELL. THERE IS NO RESEARCH DOCUMENTING LONG TERM, DAILY USE OF THESE DRUGS. WITH THEIR ABILITY TO ELEVATE BLOOD PRESSURE, THEY MIGHT HASTEN ARTERIOSCLEROSIS (HARDENING OF THE ARTERIES) AND HAVE DELETERIOUS EFFECTS ON THE HEART, BRAIN, AND/OR KIDNEYS. IT IS WELL DOCUMENTED IN THE MEDICAL LITERATURE THAT SEIZURES HAVE BEEN ASSOCIATED WITH PPA. THEY COULD HAVE DELETERIOUS EFFECTS IN PERSONS WHO ARE TAKING OTHER PRESCRIPTION MEDICATIONS SUCH AS ANTI-INFLAMMATORY DRUGS, ANTI-DEPRESSANTS, AND OTHERS. PERSONS WITH THYROID DISORDERS, DIABETES, HEART OR KIDNEY DISEASE, HIGH BLOOD PRESSURE, AND/OR WHO ARE PREGNANT OR NURSING COULD BE AT INCREASED RISK WHILE USING THESE DRUGS.

YET ANOTHER HEALTH EFFECT OF "LOOK-ALIKE" DRUGS IS THE DIFFICULTY THAT THEY CREATE FOR HEALTH PROFESSIONALS WHEN ATTEMPTING TO IDENTIFY THE DRUG(S) RESPONSIBLE FOR AN OVERDOSE VICTIM'S DISORIENTED OR COMATOSE STATE. IF AN OVERDOSE PATIENT CANNOT TELL US THAT HE TOOK "LOOK-ALIKES", IT IS OFTEN QUITE DIFFICULT FOR HEALTH PROFESSIONALS TO TELL WHETHER HE (SHE) HAS TAKEN PRESCRIPTION AMPHETAMINES OR

'LOOK-ALIKES'. ADDITIONALLY, THE WIDESPREAD AVAILABILITY AND ADVERTISING OF THESE DRUGS PROBABLY REINFORCES THE MENTALITY OF 'TAKE A PILL FOR EVERY ILL' WHICH IS ALREADY SO PREVALENT IN OUR SOCIETY. SINCE MANY USERS OF THESE DRUGS ARE OF JUNIOR-HIGH AND HIGH SCHOOL AGE, THIS IS ESPECIALLY DELETERIOUS. (21)

TO SUMMARIZE, THE ADVERSE EFFECTS OF 'LOOK-ALIKE' STIMULANTS, AS I SEE THEM, ARE AS FOLLOWS:

1) THEY CAN CAUSE HIGH BLOOD PRESSURE WHICH MAY LEAD TO STROKES, SEIZURES, AND TOXIC REACTIONS.
2) THE LONG-TERM EFFECTS OF THEIR USE IS UNDOCUMENTED.
3) THEY CAN INTERACT WITH OTHER MEDICATIONS ENHANCING THEIR TOXIC POTENTIAL.
4) THEY ARE DIFFICULT TO DISTINGUISH FROM PRESCRIPTION AMPHETAMINES.
5) THEY ARE BEING USED LARGELY BY YOUNG PEOPLE AND MAY FOSTER A PHILOSOPHY THAT 'DRUGS ARE O.K.'.

IT IS MY SINCERE HOPE THAT THE COMMITTEE WILL TAKE ACTION WHICH WOULD RESULT IN THE REMOVAL OF THESE DRUGS FROM THE LEGAL MARKETPLACE.

RESPECTFULLY SUBMITTED BY:

Barry M. Diskant, M.D.

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EMERGENCY PHYSICIAN,
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(22

APPENDIX I

TABLE I - OVER-THE-COUNTER MEDICATIONS CONTAINING PHENYLPROPANOLAMINE

A.R.M. ALLERGY RELIEF MEDICINE TABLETS (MENLEY AND JAMES)
ALLEREST HEADACHE STRENGTH TABLETS (PHARMACRAFT)
ALLEREST TABLETS AND CAPSULES (PHARMACRAFT)
ANOREXIN CAPSULES (SDA PHARMACEUTICALS)
ANOREXIN ORE-SPAN CAPSULES (SDA PHARMACEUTICALS)
APPEDRINE, MAXIMUM STRENGTH (THOMPSON MEDICAL)
BAYER CHILDREN'S COLD TABLETS (GLENBROOK)
BAYER COUGH SYRUP FOR CHILDREN (GLENBROOK)
C 3 COUGH COLD CAPSULES (MENLEY AND JAMES)
CCP TABLETS (MEDIQUE)
CHILDREN'S HOLD (BEECHAM PRODUCTS)
CODEXIN EXTRA STRENGHT CAPSULES (ARCO)
COMTREX (BRISTOL-MYERS)
CONGESPRIN LIQUID COLD MEDICINE (BRISTOL MYERS)
CONTAC CAPSULES (MENLEY AND JAMES)
CONTAC JR. CHILDREN'S COLD MEDICINE (MENLEY AND JAMES)
CONTROL CAPSULES (THOMPSON MEDICAL)
CORICIDIN CHILDREN'S COUGH SYRUP (SCHERING)
CORICIDIN 'D' DECONGESTANT TABS (SCHERING)
CORICIDIN EXTRA STRENGTH SINUS HEADACHE TABLETS (SCHERING)
CORYBAN - D CAPSULES (PFIPHARMECS)
DAYCARE MULTI-SYSTEM COLDS MEDICINE CAPSULES (VICKS HEALTH CARE)
DAYCARE MULTI-SYSTEM COLD MEDICINE (VICKS HEALTH CARE)
DEX-A-DIET LITE TIME RELEASE CAPSULES (O'CONNOR)
DEX-A-DIET II TIME RELEASE CAPSULES (O'CONNOR)
DEXATRIM AND DEXATRIM EXTRA STRENGTH (THOMPSON MEDICAL)
DIETAC DIET AID CAPSULES (MENLEY AND JAMES)
DIETAC DIET AID DROPS (MENLEY AND JAMES)
DIETAC DIET AID TABLETS (MENLEY AND JAMES)
DIETAC ONCE-A-DAY MAXIMUM STRENGTH DIET AID CAPSULES (MENLEY AND JAMES)
DIETAC TWICE-A-DAY MAXIMUM STRENGTH DIET AID CAPSULES (MENLEY AND JAMES)
DORCOL PEDIATRIC COUGH SYRUP (DORSEY)
DRISTAN DECONGESTANT/ANTIHISTAMINE/ANALGESIC CAPSULES (WHITEHALL)
D-SINUS CAPSULES (LASER)
E-Z TRIM (FOX)
4-WAY COLD TABLETS (BRISTOL-MYERS)

TABLE I CONTINUED

FORMULA 44D DECONGESTANT COUGH MIXTURE (VICKS HEALTH CARE)

NALDECON-DX PEDIATRIC SYRUP (BRISTOL)

NALDECON EX PEDIATRIC DROPS (BRISTOL)

NOVAHISTINE COLD TABLETS (DOW PHARMACEUTICALS)

NOVAHISTINE ELIXIR (DOW PHARMACEUTICALS)

ORNACOL CAPSULES (MENLEY AND JAMES)

ORNEX CAPSULES (MENLEY AND JAMES)

P.V.M. APPETITE CONTROL CAPSULES (J. B. WILLIAMS)

P.V.M. APPETITE SUPPRESSANT TABLETS (J. B. WILLIAMS)

PROLAMINE CAPSULES, SUPER STRENGTH (THOMPSON MEDICAL)

ROBUTUSSIN-CF (ROBINS)

ST. JOSEPH COLD TABLETS FOR CHILDREN (PLOUGH)

SINAREST TABLETS (PHARMACRAFT)

SINE-AID SINUS HEADACHE TABLETS (MCNEIL CONSUMER PRODUCTS)

SINE-OFF EXTRA STRENGTH SINUS MEDICINE NON-ASPIRIN CAPSULES (MENLEY & JAMES

SINE-OFF EXTRA STRENGTH SINUS MEDICINE NON-ASPIRIN TABLETS (MENLEY & JAMES)

SINE-OFF SINUS MEDICINE TABLETS - ASPIRIN FORMULA (MENLEY & JAMES)

SINUTAB EXTRA STRENGTH CAPSULE FORMULA (WARNER-LAMBERT)

SINUTAB EXTRA STRENGTH TABLETS (WARNER-LAMBERT)

SINUTAB TABLETS (WARNER-LAMBERT)

SINUTAB II TABLETS (WARNER-LAMBERT)

SUCRETS - COLD DECONGESTANT FORMULA (BEECHAM PRODUCTS)

SUPER ODRINEX (FOX)

TRIAMINIC EXPECTORANT (DORSEY)

TRIAMINIC SYRUP (DORSEY)

TRIAMINIC-DM COUGH FORMULA (DORSEY)

TRIAMINICIN CHEWABLES (DORSEY)

TRIAMINICIN TABLETS (DORSEY)

TRIAMINICOL DECONGESTANT COUGH SYRUP (DORSEY)

TUSSAGESIC TABLETS AND SUSPENSION (DORSEY)

URISINUS INLAY-TABS (DORSEY)

VICKS FORMULA 44D DECONGESTANT COUGH SYRUP (VICKS HEALTH CARE)

APPENDIX III

(24)

TABLE II - PRESCRIPTION MEDICATIONS CONTAINING PHENYLPROPANOLAMINE OR PHENYLPROPANOLAMINE HYDROCHLORIDE

ANATUSS TABLETS & SYRUP (MAYRAND)
ANATUSS TABLETS & SYRUP WITH CODINE (MAYNRAND)
ANOREXIA CAPSULES (SDA PHARMACEUTICALS)
ANOREXIN ONE-SPAN CAPSULES (SDA PHARMACEUTICALS)
BROCON C.R. TABLETS (FOREST)
BROCON CHEWABLE TABLETS (FOREST)
BROPHENTAPP T.D. TABLETS (GENEVA)
CENADEX (CENTRAL PHARMACAL)
CODIMAL EXPECTORANT (CENTRAL PHARMACAL)
CONEX (O'NEAL, JONES & FELDMAN)
CONEX WITH CODEINE (O'NEAL, JONES & FELDMAN)
CORICIDIN DEMILETS FOR CHILDREN (SCHERING)
CPROCODOM SINUS HEADACHE TABLETS (SCHERING)
DAYCARE DAYTIME COLDS MEDICINE-LIQUID (VICKS HEALTH CARE)
DECON-AID TR CAPSULES (PREMO)
DECON-TUSS TR CAPSULES (PREMO)
DEHEST (O'NEAL, JONES & FELDMAN)
DEPROHEST EXPECTORANT WITH CODEINE (GENEVA)
DEXTROTUSSIN SYRUP (LAMODA)
DIMETONE EXPECTORANT (ROBINS)
DIMETONE EXPECTORANT - DC (ROBINS)
DIMETAPP ELIXIR (ROBINS)
DIMETAPP EXTENTABS (ROBINS)
ENTEX CAPSULES AND LIQUID (BAYLOR)
ENTEX LA TABLETS (BAYLOR)
FIOGESIC TABLETS (SANDOX)
HISTABID DURACAP (GLAXO)
HISTALET FORTI TABLETS (REID-PROVIDENT)
HISTATAPP ELIXIR (UPSHER-SMITH)
HISTATAPP T.D. TABLETS (UPSHER-SMITH)
HYCOMINE PEDIATRIC SYRUP (ENDO)
HYCOMINE SYRUP (ENDO)
KRONOHIST KRONOCAPS (FERNDALE)
LEDER-BP (LEDERLE)
LEDER-CC SEQUELS (LEDERLE)
LEDER-CPI SEQUELS (LEDERLE)
NALDECON (BRISTOL)

.TABLE II CONTINUED

(25)

NAPRIL PLATEAU CAPS (MARON)
NILCOL TABLETS & ELIXIR (HEALTH CARE INDUSTRIES)
NOLAMINE TABLETS (CARNICK)
NOREL PLUS CAPSULES (MEDICS)
NOREL PLUS INJECTION (MEDICS)
NOVAHISTINE DH (DOW PHARMACEUTICALS)
NOVAHISTINE EXPECTORANT (DOW PHARMACEUTICALS)
OBESTAT LONG-ACTING CAPSULES (LEMMON)
ORNADE SPANSULE CAPSULES (SMITH, KLINE & FRENCH)
ORNADE 2 LIQUID FOR CHILDREN (SMITH, KLINE & FRENCH)
PHENYLPROPAVOLAMINE HCI T.D. CAPSULES (GENEVA)
POLY-HISTINE EXPECTORANT, PLAIN (BOCK)
POLY-HISTINE EXPECTORANT WITH CODEINE (BOCK)
POLY-HISTINE D CAPSULES (BOCK)
POLY-HISTINE D ELIXIR (BOCK)
PROLAMINE CAPSULES, SUPER STRENGTH (THOMPSON MEDICAL)
PROTID (LASALLE)
PUREBROM COMPOUND ELIXIR (PUREPAK)
PUREBROM COMPOUND TABLETS (PUREPAK)
RESAID T.D. CAPSULES (GENEVA)
RHINDECON CAPSULES (MCGREGOR)
RHINDECON-G CAPSULES (MCGREGOR)
RHNEX D-LAY (LEMMON)
RHINOLAR CAPSULES (MCGREGOR)
RHINOLAR-EX CAPSULES (MCGREGOR)
RHINOLAR-EX 12 CAPSULES (MCGREGOR)
ROBITUSSIN-CF (ROBINS)
RU-TUSS EXPECTORANT (BOOTS)
RU-TUSS PLAIN (BOOTS)
RU-TUSS TABLETS (BOOTS)
RU-TUSS WITH HYDROCODONE (BOOTS)
S-T FORTE SYRUP & SUGAR FREE (SCOT-TUSSIN)
SINUBID (PARKE-DAVIS)
SINULIN TABLETS (CARNICK)
TRIAMINIC EXPECTORANT DH (DORSEY)
TRIAMINIC EXPECTORANT WITH CODEINE (DORSEY)
TUSEQUELIN (CIRCLE)
TUSS-ORNADE (SKF)
VOXIN-PG (NORWICH-EATON)

APPENDIX III

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APPENDIX G

The Proprietary Association
1700 PENNSYLVANIA AVENUE, N.W. / WASHINGTON, D. C. 20006 / PHONE (202) 393-1700

STATEMENT OF THE PROPRIETARY ASSOCIATION

Public Hearing on "Look-Alike" Drugs
Before the U.S. House of Representatives
Select Committee on Narcotics Abuse and Control

November 30, 1981

Preface

The following statement is submitted on behalf of The Proprietary Association, a 100-year old trade association, the active members of which are engaged in the manufacture and distribution of nonprescription or over-the-counter (OTC) medicines. OTC medicines are intended for use by the consumer for the treatment of minor, self-limiting ailments or disorders, such as headache, acid indigestion, colds symptoms, minor skin irritations, and so forth. They include such products as St. Joseph's Aspirin, Vicks Cough Syrup, Noxzema Skin Cream, Tums, and many others. The Association's members are subject to the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301, et. seq.], as enforced by the Food and Drug Administration.

The Importance of Repsonsible Self-Medication

Nonprescription medicines are the first line of defense in the nation's total health care system. They are used by consumers for the treatment of ailments which are minor and which experience tells us are self-limiting ills which do not require diagnosis and treatment by a physician. The Food and Drug Administration's Commissioner, Arthur Hull Hayes, Jr., M.D., has spoken of the importance of nonprescription medicines:

> "Nonprescription drugs occupy an essential place in health care. The ability of Americans to select, buy, and use over-the-counter products to treat conditions that do not require the attention of a doctor is, I believe, a cornerstone of our health care system and of our policy for consumer health protection.
>
> Our job, both industry's and FDA's, is to see that the cornerstone remains firmly in place, and that means that the proprietary drug industry needs to maintain its

. . . /

> high standard in the quality, manufacture, and marketing of OTC drugs, and that FDA needs to be both vigilant and efficient in carrying out its responsibilities as the public agency charged with regulating OTC drugs." Statement of Arthur Hull Hayes, Jr., M.D., Commissioner of Food and Drugs, to The Proprietary Association, May 11, 1981.

Responsible self-medication performs valuable and even crucial functions for individuals, the health care system, and the economy. For the individual, it is a familiar, inexpensive, and convenient method of treating common discomforts. For the health care system, it provides a shield against a deluge of visits to health professionals for minor, self-limiting disorders. For the national economy, it helps contain the demand for primary care and, in turn, the total cost of formal medical services. As the U.S. Department of Commerce stated:

> "Self-medication with proprietary drugs is a significant factor in the U.S. health care scheme. Escalating costs of health care create a greater need for low cost self-medication than ever before. Seventy-five percent of all illnesses and injuries are initially treated through self-care and OTC medications. If only a small percentage of self-treatment was shifted to medical practitioners, the patient load would disrupt the U.S. health care system." U.S. Industrial Outlook 1978, U.S. Department of Commerce, January, 1978, page 131.

OTC Labeling

Because OTC medicines are designed for use by consumers without medical supervision, federal and state laws and/or regulations require and have for many years required that they contain considerable labeling information for the benefit of consumers. This information includes:

(1) The product name;
(2) a statement of identity;
(3) a list of ingredients;
(4) the net quantity of the contents;
(5) the name and address of the manufacturer, packer, or distributor;
(6) the indications for use;
(7) directions and dosage instructions;
(8) warnings and cautionary statements;
(9) drug interaction precautions, if any, and
(10) an expiration date.

The Association is well aware of the critical function which the labeling of an OTC serves in the appropriate and responsible use of OTC medicines. Over the years the Association has made available to consumers through pharmacists thousands of pamphlets titled "Read the Label on Nonprescription

. . . /

Medicines" or, more recently, "Medicine Labels and You." In addition, the Council on Family Health, a non-profit organization funded by many of the Association's members, has sought and obtained millions of dollars worth of public service announcements on radio and television which urge consumers to read the label on OTC medicines.

OTC/Controlled Substance Look-Alikes

The subject of this hearing is the manufacture of perhaps legally formulated OTC medicines so as to make them resemble controlled substances and promoting them as such, as well as promoting OTCs for ingestion in quantities which vastly exceed their recommended dosage. The Association and its members are opposed to such practices because they necessarily involve the marketing of OTCs without adequate labeling or encourage the disregard of OTC labeling as well as encourage the use of OTCs for inappropriate conditions. In the process, they damage the public's confidence in OTCs as the safe and effective medicines which they are if they are used as directed.

The Proprietary Association was first asked to assist in combating the marketing of OTC/controlled substance look-alikes in 1979, when it was invited to and did testify before a legislative committee in Oregon. Earlier this year the Association testified in Wisconsin, and since then has organized and keeps updated a compilation of OTC/controlled substance look-alike legislation which has been considered or enacted in the states (attached as Appendix I). The Association has distributed this material to pharmaceutical associations and others in several states, including Colorado, Iowa, Kentucky, Louisiana, Michigan, Nebraska, New York, and Washington.

The Association also plans to discuss the issue with the Drug Enforcement Administration, which is in the process of drafting a model state bill to prohibit the practice. The Association notes, however, that the practice is illegal under several provisions of existing federal law — specifically the Federal Food, Drug, and Cosmetic Act (see Appendix II). Accordingly, on September 21, the Association formally requested that FDA take action against the practice (See Appendix III). As the Select Committee is aware, on September 30, 1981, FDA announced the seizure as OTC/controlled substance look-alikes of the products of nine manufacturers in five states on September 30, 1981. The Association also notes that the Post Office Department has obtained a number of injunctions or consent agreements which prohibit persons from receiving OTC/controlled substance look-alikes through the mails.

Conclusion

Responsible self-medication for minor, transient ills is indeed a cornerstone of our nation's health care system. As FDA Commissioner Hayes has pointed out, however:

> "[S]elf-medication will and should continue to play a very important role in meeting the health needs

. . . /

> of most people, but only as long as they can feel sure that the products they select and use will perform as they say they will, that they are manufactured in accordance with high standards and rigorous quality control, and that they can be used with the utmost confidence in their safety." Statement of Arthur Hull Hayes, Jr., M.D., to the Sixth General Assembly of the World Federation of Proprietary Medicine Manufacturers, Ottawa, Canada, October 12, 1981.

The Association strongly echoes Commissioner Hayes' admonition, believing that the manufacture and marketing of OTC/controlled substance look-alikes can only damage the public's confidence — a well-founded confidence — that OTC medicines are safe and effective when used for the purposes, in the amounts, and under the conditions described in the labeling.

Sincerely,

THE PROPRIETARY ASSOCIATION

Daniel F. O'Keefe, Jr.
Senior Vice President, General Counsel
and Secretary

DOK:kbh
Attachments: Appendix I, Controlled Substances/Look-Alike Legislation
Appendix II, The Proprietary Association's Memorandum titled "The Sale of an OTC Drug Outside of Its Original Container Under the Representation That It is A Controlled Substance Is Illegal Under the Federal Food, Drug, and Cosmetic Act"
Appendix III, September 21, 1981 letter from The Proprietary Association to FDA Chief Counsel Thomas Scarlett

APPENDIX I

THE PROPRIETARY ASSOCIATION

The following states have enacted look-alike laws during the 1981 session:

Arkansas S.B. 149 - sale of a noncontrolled substance represented to be a controlled substance is made a felony.

Colorado H.B. 1577 - sale of counterfeit controlled substances is a Class 4 felony.

Connecticut H.B. 5466 - fraudulent delivery of a noncontrolled substance is a Class D felony.

Delaware S.B. 230 - unlawful delivery of a noncontrolled substance is a felony.

Florida S.B. 31 - sale of counterfeit controlled substances is a felony or misdemeanor.

Indiana H.B. 1019 - sale of counterfeit controlled substances is a Class D felony.

Louisiana H.B. 422 - sale of a noncontrolled substance represented to be a controlled substance is punishable by a fine and imprisonment.

Maryland H.B. 622 - unlawful sale of counterfeit controlled substances is a felony.

North Carolina H.B. 1204 - defines a counterfeit controlled substance, no penalties are provided.

Oregon S.B. 656 - unlawful delivery of counterfeit controlled substances is a felony.

South Dakota H.B. 1153 - prohibits the sale of noncontrolled substances purported to be controlled substances and sets the penalties as a misdemeanor.

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10/15/81

The following look-alike bills were proposed in 1981, but were not enacted into law:

Florida

H.B. 140

Illinois

H.B. 1933

Kansas*

S.B. 164

Maryland

S.B. 519
S.B. 847
H.B. 695
H.B. 841
H.B. 1069

Michigan

S.B. 458

North Carolina*

H.B. 1021

Ohio*

S.B. 246
H.B. 535

Oregon

H.B. 2066

Pennsylvania

S.B. 1022
S.B. 1095

Tennessee*

S.B. 1181
H.B. 760

West Virginia

H.B. 1262

Wisconsin

S.B. 536

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*These states holdover their undisposed-of legislation to the 1982 session.

MJU:kbh
10/15/81

JUN 30 1981

HOUSE BILL NO. 1577.

BY REPRESENTATIVES Artist, Mielke, DeHerrera, Fine, Heim, Kirscht, Lillpop, Pena, Prendergast, Robb, Scherling, Spelts, Sullivan, Armstrong, Becker, Castro, Chavez, Dyer, Eberle, Hastings, Hudson, Hume, Larson, Lucero, Massari, McCroskey, Minahan, Neale, Paulson, Rogers, Shoemaker, Taylor, and Younglund;
also SENATORS Ezzard, Meiklejohn, Schaefer, Zakhem, MacManus, Phelps, Strickland, and Yost.

CONCERNING COUNTERFEIT CONTROLLED SUBSTANCES.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Part 3 of article 5 of title 18, Colorado Revised Statutes 1973, 1978 Repl. Vol., as amended, is amended BY THE ADDITION OF A NEW SECTION to read:

18-5-306. Counterfeit or imitation controlled substances. (1) As used in this part 3, unless the context otherwise requires:

(a) "Controlled substances" means a narcotic drug, as defined in section 12-22-301 (16), C.R.S. 1973, or a dangerous drug, as defined in section 12-22-403 (4), C.R.S. 1973, or any drug or other substance or an immediate precursor which is declared to be a controlled substance under part 3 of article 22 of title 12, C.R.S. 1973.

(b) "Counterfeit or imitation controlled substances" means any substance which is not a controlled substance, but which is expressly or impliedly represented to be a controlled substance and which is of such nature, packaging, or appearance as to lead a reasonable person to believe that the substance is a controlled substance.

Capital letters indicate new material added to existing statutes; dashes through words indicate deletions from existing statutes and such material not part of act.

State of Connecticut Proposed Bill 5466 An Act Concerning Fraudulent Delivery of Noncontrolled Substances

Connecticut #0576,

STATE OF CONNECTICUT

Proposed Bill No. 5466 Page 1

Referred to Committee on Public Health

LCO No. 361

Introduced by REP. DEZINNO, 84TH DIST.

General Assembly,

January Session, A.D., 1981

AN ACT CONCERNING FRAUDULENT DELIVERY OF NONCONTROLLED SUBSTANCES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

That section 19-473 of the general statutes be amended to provide that the knowing delivery or knowing attempt to deliver a noncontrolled substance (1) upon the express representation that such substance is a controlled substance or that such substance is of such nature or appearance that it may subsequently be distributed as a controlled substance or (2) under circumstances which would lead a reasonable person to believe that such substance was a controlled substance, shall be punishable as a class D felony

STATEMENT OF PURPOSE: To increase the penalty for delivery of noncontrolled substances in circumstance which indicate that they ae controlled substances. Use of substances such as caffeine in the mistaken belief that they are amphetamines or other controlled substances may result in a fatal overdose if the user later comes into possession of the real controlled substance.

THE PROPRIETARY ASSOCIATION

State of Florida Senate Bill 31
An Act Relating to Counterfeit
Controlled Substances

SENATE BILL 31 BY BEARD

A bill to be entitled

An act relating to counterfeit controlled substances; prohibiting the sale of substances falsely represented as controlled substances; prohibiting the sale, manufacture, delivery, and possession of counterfeit or mislabeled controlled substances; prohibiting the possession, sale, manufacture, and delivery of devices intended to be used in mislabeling controlled substances or in falsely labeling substances as controlled substances; providing penalties; providing an effective date.

THE PROPRIETARY AS
REGIN
RESOLUT

Be It Enacted by the Legislature of the State of Florida:

Section 1. It is unlawful for any person to agree, consent, or in any manner offer to unlawfully sell to any person a controlled substance named or described in s. 893.03, Florida Statutes, and then sell to such person any other substance in lieu of such controlled substance. Any person who violates this section with respect to:

(1) A controlled substance named or described in s. 893.03(1), (2), (3), or (4), Florida Statutes, is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, Florida Statutes.

(2) A controlled substance named or described in s. 893.03(5), Florida Statutes, is guilty of a misdemeanor of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, Florida Statutes.

Section 2. (1) It is unlawful for any person to sell, manufacture, or deliver or to possess with intent to sell,

CODING: Words in struck through type are deletions from existing law; words underlined are additions.

Florida S.B. 31

22-52-81

manufacture, or deliver a counterfeit controlled substance. Any person who violates this subsection with respect to:

(a) A controlled substance named or described in s. 893.03(1), (2), (3), or (4), Florida Statutes, is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, Florida Statutes.

(b) A controlled substance named or described in s. 893.03(5), Florida Statutes, is guilty of a misdemeanor of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, Florida Statutes.

(2) It is unlawful for any person to possess, sell, manufacture, or deliver, any punch, die, plate, stone, or other device intended to be used in printing, imprinting, or reproducing a trademark, trade name, or other identifying mark, imprint, or number, or any likeness thereof, upon a substance, or its container or label, so as to render such substance a counterfeit controlled substance. Any person who violates this subsection is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, Florida Statutes.

(3) For purposes of this section, "counterfeit controlled substance" means:

(a) A controlled substance named or described in s. 893.03, Florida Statutes, which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or number, or any likeness thereof, of a manufacturer other than the person who in fact manufactured the controlled substance; or

(b) Any substance which is falsely identified by its container or labeling as a controlled substance named or described in s. 893.03, Florida Statutes.

CODING: Words to struck through type are deletions from existing law; words underlined are additions.

State of North Carolina House Bill 1204
An Act to Define " ounterfeit Controlled Substance"

(41)

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 1981
RATIFIED BILL

CHAPTER 732

HOUSE BILL 1204

AN ACT TO DEFINE "COUNTERFEIT CONTROLLED SUBSTANCE" IN THE NORTH CAROLINA CONTROLLED SUBSTANCES ACT.

The General Assembly of North Carolina enacts:

Section 1. G.S. 90-87(6) is rewritten to read:

"(6) 'Counterfeit controlled substance' means:

a. A controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports, or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser; or

b. Any substance which is by any means intentionally represented as a controlled substance. It is evidence that the substance has been intentionally misrepresented as a controlled substance if the following factors are established:

THE PROPRIETARY ASSOCIATION
NOV 6 1981

THE PROPRIETARY ASSOCIATION

The Sale of an OTC Drug Outside of Its Original Container Under the Representation That It Is A Controlled Substance Is Illegal Under the Federal Food, Drug, Cosmetic Act

Introduction

Recently state drug enforcement authorities in several states have informed The Proprietary Association that some unscrupulous individuals in those states purchase OTC medicines which resemble controlled substances, remove them from their original containers, and sell them outside conventional retail channels under the representation they are controlled substances. The question has been asked whether this practice is actionable under federal and/or state law.

Summary

Many states have laws patterned after the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301, et. seq.], which regulates the manufacture packaging, and distribution of drugs in interstate commerce. All states have laws which regulate the practice of pharmacy and the sale of drugs at retail. However, since not all state food, drug, and cosmetic laws are identical to the Federal Act, and not all pharmacy acts are identical (or in many cases even nearly identical) to each other, a brief analysis of the legality of the above-described practice can include a review only of the applicable provisions of the Federal Act. A complete analysis would require a separate examination of each applicable state law. In general, however, it can be said that if the above-described practice is illegal under Federal law, it will be found to be illegal under state law.

The sale of an OTC drug outside of its original container under the representation that it is a controlled substance violates at least two, and in some cases three provisions of the FDC Act, even if interstate commerce is not involved. If interstate commerce is involved, the practice violates from one to three additional provisions. All violations are felonies, subjecting the individual to penalties of imprisonment for up to three years and/or a fine of up to $10,000. The provisions violated by the above-described practice are the following subsections of the Prohibited Acts Section of the Act, Section 301:

(l) Rendering a drug adulterated or misbranded by removing its labeling or otherwise causing it to be adulterated or misbranded:

> Section 301. The following acts and the causing thereof are prohibited:
>
> * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(2) Failing to register as a drug "manufacturer" [defined to include a person who repackages or otherwise changes the container, wrapper, or labeling of any drug package]:

> Section 301. The following acts and the causing thereof are prohibited:
>
> * * *
>
> (p) The failure to register in accordance with section 510, the failure to provide any information required by section 510(j) or 510(k), or the failure to provide a notice required by section 510 (j)(2).

(3) Causing a drug to be a counterfeit drug by imprinting on it or its container the trademark, trade name, or other identifying mark of another drug:

> Section 301. The following acts and the causing thereof are prohibited:
>
> * * *
>
> (i)(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(4) Adulteration or misbranding of a drug in interstate commerce, or introduction, delivery for introduction, or receipt in interstate commerce of an adulterated or misbranded drug:

> Section 301. The following acts and the causing thereof are prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.
>
> (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

Discussion

(1) Rendering a drug adulterated or misbranded by removing its labeling or otherwise causing it to be adulterated or misbranded

The FDC Act is to a large extent a pure food and drug law, focusing on the question whether a drug is "adulterated." In general, an individual

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who repackages a drug under insanitary conditions or conditions which reduce its quality or strength or which do not comport with "current good manufacturing practice," or who repackages it in an unsuitable container, violates Section 301(k). Section 301(k) prohibits the doing of any act with respect to a drug which results in its being adulterated. Under Section 501, a drug is adulterated:

> (a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health. . . .
>
> * * *
>
> (d) If it is a drug and any substance has been. . . mixed or packed therewith so as to reduce its quality or strength . . . .

Thus, an individual who repackages an OTC drug under insanitary conditions violates Section 501(a)(1). An individual who fails to conform to the detailed requirements of the Food and Drug Administration's "current good manufacturing practice" regulations violates Section 501(a)(2)(B). (The FDA's "current good manufacturing practice" regulations include stringent record keeping, production, and quality control requirements, as well as the requirement that the container of an OTC carry an expiration date for the drug.) If the individual uses an unsuitable container, he violates Section 501(a)(3), and if he mixes an inappropriate substance with the drug, he violates Section 501(d).

The FDC Act is not only a pure food and drug law, however, but also a labeling law, which focuses on the question whether a drug is "misbranded." If a person causes a drug to be inaccurately or incompletely labeled or to be unlabeled altogether, he has similarly violated Section 301(k), which prohibits the doing of any act with respect to a drug which results in its being misbranded. Under Section 502, an OTC drug is misbranded:

> (a) If its labeling is false or misleading in any particular.
>
> (b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count . . . .
>
> * * *
>
> (e)(1) If it is a drug, unless (A) its label bears . . . (i) the established name . . . of the drug, if such there be, and (ii) in case it is fabricated from two or more ingredients, the established name of

each active ingredient, including the quantity, kind, and proportion of any alcohol. . . .

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may dangerous to health, or against unsafe dosage or methods or duration of administration or application . . . .

* * *

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

* * *

(o) If it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 510, "if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k)....

(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packing Act of 1970.

Thus, an individual who sells an OTC drug with no labeling violates Section 502(f). If labeling is present but misleading as to the true identity of drug, he violates Sections 502(a), (e), and (i)(2) and (3). If labeling is present and accurately identifies the drug but fails to identify the name and place of business of the manufacturer, packer, or distributor or the net quantity of the contents, the individual violates Section 502(b).

If the drug is packaged in a container which is made, formed, or filled so as to be misleading, he violates Section 502(i)(1). If the drug is acetaminophen, aspirin, or one of certain iron-containing preparations and is not packaged with a safety closure, as is required by the Poison Prevention Packaging Act of 1970, he violates Section 502(p).

(2) Failing to register as a drug "manufacturer" [defined to include persons who repackage or otherwise change the container, wrapper, or labeling of any drug package]

Section 510 of the Act, passed as the Drug Listing Act of 1972, seeks to ensure that the Food and Drug Administration knows who is performing "manufacturing" operations on drugs. The term "manufacturing" is defined to include:

> "repackaging or otherwise changing the container, wrapper, or labeling of any drug package . . .in furtherance of the distribution of the drug . . .from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. . . ." 21 U.S.C. 360.

The method chosen by Congress to ensure that FDA has such information is to require an annual registration by everyone (except four classes of persons not relevant here) who owns an establishment where such activities are conducted, and an initial submission by that person to FDA, to be revised periodically, listing the drugs "manufactured" by that person, the label and a representative sample of the labeling of such drugs, and other information both mandatory and optional with FDA.

Thus, an individual who performs a repackaging operation, such as removing an OTC drug from its original container and selling it in another container or in no container violates Section 301(p) if he fails to register and update his submissions in the time intervals and with the information required by law or by FDA.

(3) Causing a drug to be a counterfeit drug by imprinting on it or its container the trademark, trade name, or other identifying mark of another.

Section 301(i)(3) prohibits the doing of any act which causes a drug to be a "counterfeit" drug, defined in Section 201(g)(2) as follows:

> (2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

Section 301(i)(3) thus applies in the perhaps limited instances in which the seller, in the above-described situation, identifies the drug or its container as that of a controlled substance by a mark, imprint, logo, etc. on the drug or container itself.

(4) Adulteration or misbranding of a drug in interstate commerce or introduction, delivery for introduction, or receipt in interstate commerce of an adulterated or misbranded drug.

Section 301(a), (b), and (c) prohibit the acts listed above, but only if interstate commerce is involved, that is, only if the drugs cross state lines

in furtherance of the operations or if can reasonably be concluded that the drug has crossed state lines in furtherance of the operation. The operations described to The Proprietary Association of breaking down the original packages of OTC drugs and selling them as controlled substances seem to be of the type which occur wholly intrastate, making Sections 301(a), (b), and (c) of less relevance than the statutes described earlier.

Conclusion

Section 302 of the Act allows the government to seek an injunction against an individual in all of the above-described situations except that of counterfeiting. However, the scienter element involved in the transaction of selling OTC drugs by representing them as controlled substances brings into play the more likely sanction, covered under Section 303(b) of the Act which subject inviduals who violate any provision of Section 301 "with the intent to defraud or mislead" to penalties of up to three years in prison and/or $10,000 in fines. Finally, Section 304(a) subject the violative drugs to seizure.

In view of the pervasive nature of the adulteration and misbranding provisions of the FDC Act, it would appear that the sale of an OTC drug outside of its original container under the representation that it is a controlled substance is actionable by Federal agents under the FDC Act and by state agents under any state acts with similar provisions.

- o0o -

GMF/sbm
5/22/81

The Proprietary Association
1700 PENNSYLVANIA AVENUE, N.W. / WASHINGTON, D. C. 20006 / PHONE (202) 393-1700

September 21, 1981

Thomas Scarlett, Esq.
Chief Counsel
Food and Drug Administration
Department of Health and Human Sciences
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Scarlett:

There is evidence of an apparently growing practice in many areas of the country of the manufacture and/or distribution of tablets and capsules in such a way as to make them look like, and convince purchasers that they are, controlled substances. We are informed that, typically, these counterfeit look-alikes are manufactured to resemble controlled substances by imitating the capsule size, colors and markings of the legitimate controlled substances, that they are typically sold in large quantities (e.g., bottles of 1,000), and that they are later distributed in small quantities — without labeling — in schools, truck stops, and on street corners. Although these tablets and capsules often consist of acceptable OTC ingredients and/or combinations at legal dosage levels, they are not properly labeled — at least when sold to the ultimate consumer — as OTC medicines in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act.

As the 100-year-old trade association which represents manufacturers and distributors of non-prescription or over-the-counter medicines, this Association strongly objects to the practice outlined above. We emphasize that our members do not engage in this practice which appears not only to be illegal under existing law, but also constitutes a threat to health, and damages the public's perception of OTC medicines as safe and effective when used according to label directions. We strongly urge the FDA to investigate this practice and take action under the anti-counterfeiting and/or misbranding provisions of the Federal Food, Drug, and Cosmetic Act. (21 U.S.C §§321(g)(2), 331(i), and 352(i)).

As you know, an OTC medicine under the Federal Food, Drug, and Cosmetic Act is one which can be used safely and effectively by the consumer on the basis of its label directions, without the supervision of a physician. Because of the critically important function which the labeling of an OTC serves, the FDC Act and/or FDA regulations require that it include:

(1) the product name,
(2) a statement of identity,
(3) a list of the active ingredients,

(4) the net quantity of the contents,
(5) the name and address of the manufacturer, packer or distributor,
(6) the indications for use,
(7) directions and dosage instructions,
(8) warnings and cautionary statements,
(9) drug interaction precautions, if any, and
(10) an expiration date.

The Association appreciates the importance of labeling of an OTC. Over the years it has made available to consumers through pharmacists thousands of pamphlets titled "Read the Label on Nonprescription Medicines" or, more recently, "Medicine Labels and You." In addition, the Council on Family Health, a non-profit organization funded by many of the Association's members has sought and obtained millions of dollars worth of public service announcements on radio and television which urge consumers to read the label on OTC medicines.

The Association favors and has always favored only the appropriate use of OTC medicines; that is, their proper use in accordance with label directions. We view the practice described in this letter as harmful to the public interest. At a minimum it reduces public confidence in safe, effective, and properly labeled OTC medicines and, therefore, in appropriate self-medication.

Please let us know if we can be of assistance in this matter.

Sincerely,

Daniel F. O'Keefe, Jr.
Senior Vice President, General Counsel
and Secretary

DOK:bws

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Food and Drug Division
Rockville, MD 20857

October 1, 1981

Daniel F. O'Keefe, Jr., Esq.
Senior Vice President, General Counsel
and Secretary
The Proprietary Association
1700 Pennsylvania Avenue, N.W.
Washington, D.C. 20006

Dear Mr. O'Keefe:

Thank you for your September 21 letter expressing The Proprietary Association's concern with the problem posed by so-called look-alike drugs, i.e., OTC drugs fabricated to look like controlled substances. The Food and Drug Administration shares your organization's concern. As you know, a number of seizure actions were recently filed on behalf of the FDA, with the result that large quantities of look-alike drugs have been seized, along with manufacturing equipment in several cases. We appreciate your offer to assist FDA in dealing with the problem of look-alike drugs.

Sincerely,

Thomas Scarlett

Thomas Scarlett
Chief Counsel
Food and Drug Administration

APPENDIX H

PENNWALT CORPORATION

PENNWALT BUILDING, THREE PARKWAY, PHILADELPHIA, PENNSYLVANIA 19102

[The following correspondence was provided for the record by Pennwalt Corporation.]

December 30, 1980

The Honorable Jere Goyan
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Counterfeiting of Controlled Drugs

Dear Commissioner Goyan:

On behalf of Pennwalt Corporation,*/ I write to ask that your Agency take action to correct the serious health and safety problems created by numerous distributors engaged in the nationwide sale of capsuled drug products containing OTC ingredients that mimic prescription CNS stimulants (controlled substances). The latter include, but are not limited to, Pennwalt's Biphetamine (resinated amphetamine) and Ionamin (resinated phentermine).

Many of these drug products appear to be counterfeit, made for the primary purpose of palming them off as prescription CNS stimulants (controlled substances). These counterfeit products are typically offered as "stimulants" and are ultimately sold to consumers such as truck drivers, college and high school students, and others, at highly-inflated prices which reflect the street price premium for a "controlled substance".

*/ Pennwalt Corporation, founded in 1850, is headquartered in Philadelphia, Pennsylvania. It has annual sales, in the United States and abroad, in excess of $1,000,000,000. Its major product fields are chemicals, pharmaceuticals, dental products, and specialized equipment.

WRITER'S DIRECT DIAL NUMBER: (215) 587-7223

Similar activity has been held to constitute criminal conduct under the anti-counterfeiting provisions of the Federal Food, Drug and Cosmetic Act, (21 U.S.C. Secs. 321(g)(2), 331(i), and 333), and is within the power of the FDA to police under the drug seizure statutes (21 U.S.C. Sec. 334); see U. S. v. Cerrito, 413 F. 2d 1270, (C.A. 7, 1969). (In many instances, it appears that the mails and the telephone may have been used in the promotion and distribution of these products. Accordingly, this conduct might also be in violation of the mail fraud statute (18 U.S.C. Sec. 1341) and the wire fraud statute (18 U.S.C. Sec. 1343).)

In our view, the production and distribution of these counterfeit products threatens the integrity of the nation's drug control system, causes a serious threat to health, and presents a basic policy question as to whether our society should tolerate what prompt agency action can prevent or greatly impede. Commerce in these products provides substantial profits to those who are encouraging widespread non-medical use of such counterfeit drugs; these merchants lead the users to believe that they have purchased controlled substances which will fill the "need" the user wishes to serve, without prescription or medical supervision, and, as we discuss below, at considerable risk to the user and to society generally.

Description of Counterfeiters' Modus Operandi

The counterfeiters typically offer an array of encapsulated products, all of which contain basically the same active ingredients: caffeine, phenylpropanolamine, and/or ephedrine. Despite the identical chemical formulation of the products, however, a counterfeiter will sell them in a variety of different capsule colors and markings which closely or identically imitate the capsule size, colors, and markings of various controlled substance products. (See Attachment A)

Significantly, the counterfeiters do not promote their products by reference to their ingredient content, medical purpose, or other traditional labeling information. Instead, as shown by the enclosed typical promotional material (Attachment B), the capsules are offered for sale by their color and/or markings, i.e., the very factors which make them imitations of legitimate controlled substance drugs. Moreover, the capsules are typically sold to and through distributors in bottles of 1,000, a quantity far in excess of any individual's needs, and, ultimately intended to be illicitly and fraudulently sold on an individual capsule basis, without the required labeling, on street corners, at truck stops, and at schools.

Although the products of several legitimate drug companies have been copied, Pennwalt, in particular, has been a major target of the counterfeiters. Pennwalt's Biphetamine-20 and Ionamin-30 products have been copied in many different ways. These products are currently marketed in capsules (black and yellow, respectively) stamped with their FDA assigned National Drug Code (NDC) numbers (18-875 and 18-904, respectively), and were also marketed in capsules marked with Pennwalt's trademark "RJS" (derived from Robert J. Strasenburgh, founder of the predecessor company which originally manufactured and marketed Biphetamine and Ionamin).

Counterfeiters are now offering CNS stimulant products in black or yellow capsules marked with the number 18, the initials RJS, and variations such as RUS, RJ8, 1S, etc. Indeed, in one recent instance, the counterfeiter copied Pennwalt's NDC numbers exactly and also used a logo substantially similar to the triangular logo currently used by Pennwalt. Other counterfeits closely resemble products marketed by other legitimate manufacturers, including Fastin (phentermine), Dexedrine and Dexamyl (amphetamine). Such drugs are clearly "counterfeit drugs" within the meaning of 21 U.S.C. Sec. 321(g)(2), as they bear "the trademark, trade name, or other identifying mark, imprint ... , or any likeness thereof, of a drug manufacturer...."

Need for Nationwide Approach to Problem

It is quite evident that this counterfeiting problem goes beyond the traditional unfair competition complaint involving one company's suit against others for wrongful taking of property rights. Pennwalt has four such actions pending and has had injunctions issued in two of them, but has received information concerning far more counterfeiters.

The problem is national in scope and, unless acted upon, the existing examples of thus far successful counterfeiting clearly will invite product-line extension to counterfeiting of other scheduled substances not yet reached by the counterfeiters. Indeed, some of the distributors of counterfeit stimulants are now advertising "sleep aids" which may resemble other controlled substance products.

In the counterfeit instances we have noted, it seems clear that:

1. The existence of statutory violations is plain and clear (See United States v. All Equipment, Inc. But Not Limited to, Etc. 485 F. Supp. 39 (E. D. Mo. 1979), United States v. Cerrito, 413 F. 2d 1270, (C.A. 7, 1969).

2. The medically unsupervised use of the counterfeit capsules, in terms of quantity ingested and frequency of ingestion, and without labeling or other safeguards, raises serious public health questions.

3. The widespread availability of counterfeit capsules which mimic controlled substances has caused drug enforcement authorities to waste time, money and effort tracking down imitation products. In treating overdose or other crisis cases, the counterfeit capsules also create identification problems for emergency room and poison control center personnel.

4. The widespread availability of the counterfeit capsules also undercuts still further whatever validity the statistical drug abuse monitoring programs, such as the DAWN system, may have.

5. The counterfeiters are reaping large profits from an essentially fraudulent scheme. Sworn testimony in civil litigation brought by Pennwalt shows that in early 1980 the products in question were being sold for from $.25 to $.50 per capsule at truck stops. Delaware law enforcement personnel have informed our outside attorneys that the products are sold at a price of from $.50 to $1.00 per capsule in Delaware school yards. By contrast, documents produced in litigation indicate that distributors purchase the capsules for about $0.01 each from the formulators. These high prices can only be the result of the belief that the drugs are "illegal" controlled substances.

6. As a consumer protection agency, the FDA should move quickly against such frauds when, as here, it is in a position to do so effectively. In addition, it seems likely that thorough investigation of the matter may reveal numerous instances of tax evasion, mail or wire fraud.

Suggested Enforcement Program

For the foregoing reasons, we respectfully urge you, in cooperation with the Justice Department and local U.S. attorneys, to undertake the following actions on a priority basis:

1. Direct FDA inspectors to visit each of the companies we have identified to determine:

   (a) whether whatever drug activities they are engaged in are in accord with their FDA registration, if any;

   (b) whether they are in possession of drugs in black or yellow capsules, or other dosage forms, which mimic popular controlled-substance drugs;

   (c) whether they possess any equipment used in the manufacture of such controlled-substance look-alikes; and

   (d) their sources of supply of finished drug capsules;

   (e) their product literature, or lack thereof, as evidence of their business purposes.

2. If controlled-substance look-alike drugs and/or equipment for making such drugs are found, promptly seize the drugs and equipment under the authority of 21 U.S.C. Sec. 331 (i), 334.

3. If the establishments are not properly registered, take appropriate action.

4. Institute criminal prosecution under the counterfeiting statute against individual principals of major distributors and manufacturers.

5. In addition, undertake one or more Grand Jury investigations to identify other participants in the counterfeiting, trace the revenues from the operation, and identify other possible violations of Federal law, such as tax evasion, which seem likely to be occurring, as well as mail fraud and wire fraud (18 U.S.C. Secs. 1341 and 1343).

6. Follow up with inspections of sources of supply, seizing counterfeit capsules or equipment used in counterfeiting.

Pennwalt Corporation stands ready to cooperate with you in any way it can to expedite and facilitate such legal proceedings. Our outside attorneys have already provided to the staff of the Bureau of Drugs information concerning the identity and operation of a number of suspected counterfeiters. For your convenience, as well as that of the other Federal law enforcement personnel to whom we are sending copies of this letter, we have enclosed an updated list of companies for which we have received specific information suggesting that they are engaged in suspect activities (Attachment C). Our outside attorneys, James M. Johnstone and John B. Wyss (202/857-5000), will furnish all available information to FDA personnel on request.

Very truly yours,

J Gordon Logue

J. Gordon Logue
Senior Vice President
Secretary & General Counsel

JGL:gm
Attachments

cc: J. Richard Crout
Chief, Bureau of Drugs, FDA

Theodore E. Byers,
Associate Director for Compliance
Bureau of Drugs, FDA

Rudolph Apodaca
Director, Division of Drug Labeling
Compliance, Bureau of Drugs, FDA

Nancy L. Buc
Chief Counsel, FDA

Sanford J. Litvack
Assistant Attorney General
Antitrust Division

J. Patrick Glynn
Chief, Consumer Affairs Section, Antitrust Div.

ATTACHMENT A

EXAMPLES OF CONTROLLED SUBSTANCES COUNTERFEITS

Manufacturer	Product	Color and Markings	Counterfeits
Beecham Laboratories	Fastin (Phentermine HCl)	Fastin is marketed in a blue and clear capsule imprinted with "147".	Blue and clear capsules, often marked with 127 or 147.
Pennwalt Corporation	Biphetamine-20 (Resin complex of amphetamine and dextroamphetamine)	Biphetamine-20 is marketed in black capsules imprinted with "18-875" (current version) or "RJS" (earlier version).	Black capsules, often marked variously with "18-875," "1S 875," "18-845," "18-858," "18-658," "18-985," "RJS," "RUS," "RVJ," or "RJ8."
Pennwalt Corporation	Ionamin-30 (Phentermine resin)	Ionamin-30 is marketed in a yellow capsule imprinted with "18-904" (current version) or "RJS" (earlier version).	Yellow capsules, often marked variously "18-904," "18-704," "C8 704," "RJS," "RUS," "RJ8," or "RVJ".
Smith, Kline & French	Dexamyl (Dextroamphetamine sulfate and amobarbitol)	Dexamyl is marketed in a green and clear capsule imprinted with "D92."	Green and clear capsules, often marked 092.
Smith, Kline & French	Dexedrine (Dextroamphetamine sulfate)	Dexedrine is marketed in a brown and clear capsule imprinted with E 14 and containing colored beads.	Brown and clear capsules containing colored beads.
Smith, Kline & French	Eskatrol (Dextroamphetamine sulfate and prochloro-perazine)	Eskatrol is marketed in a white and clear capsule imprinted with "J66" and containing colored beads.	White and clear capsules containing colored beads.

APPENDIX I

[The following materials were submitted for the record by the Association of Food and Drug Officials. Organized in 1896, the Association is an international, nonprofit organization concerned with the development and enforcement of uniform food, drug and other consumer protection laws.]

POSITION PAPER ON CONTROL OF "LOOK-A-LIKE" DRUGS

Prepared by AFDO Drug, Device, & Cosmetic Committee

The manufacture and sale of drugs which imitiate narcotic and non-narcotic controlled substances (termed "look-a-likes") seems to be reaching epidemic proportions, and it appears that the major drug related issue under consideration in state legislatures at this time is concerned with the "look-a-like" drug problem.

"Look-a-like" drugs represent a potential for serious overdose when they are sold indiscriminately in the illegal drug market by street vendors. Some people believe the high school teenager constitutes a major illicit market for these products. Since some look-a-like drugs contain ingredients which may be sold over the counter, they do not produce the usual "high" and several dosage units may be consumed. When the user then gets the real thing and consumes the look-a-like dosage, a serious drug overdose may occur.

In addition to the potential overdose problem, other serious side effects and problems exist when any drug is consumed indiscriminately and without the proper precautionary labeling.

Look-a-like drugs are advertised openly in a number of the drug culture magazines. Many of these drugs appear to be properly labeled when they leave the manufacturer except that they are made to resemble a controlled substance.

The following states have proposed legislation regarding look-a-like drugs during the current sessions (Delaware's legislation has beeen enacted and used):

Arkansas	Minnesota
Colorado	New Hampshire
Connecticut	New Mexico
Florida	Oklahoma
Indiana	Oregon
Kansas	South Dakota
Maryland	Tennessee

The attachment contains suggested guidelines for the development of legislation to prohibit the sale of <u>imitation</u> (look-a-like) controlled drugs.

GUIDELINES FOR LEGISLATION
TO
PROHIBIT THE SALE
OF
IMITATION (LOOK-A-LIKE) CONTROLLED SUBSTANCES

Prohibited Acts

Except as otherwise authorized by law, no person shall:

1. Manufacture, process, or store a controlled drug substance or any substance which resembles, imitates, or has the appearance of a controlled substance whether or not it contains a controlled substance.

2. Sell, furnish, transport, or give, or to offer or arrange to sell, furnish, transport, or give a controlled drug substance or any substance which resembles, imitates, or has the appearance of a controlled drug substance whether or not it contains a controlled drug substance.

Definitions and Standards

1. A substance shall be deemed to resemble, imitate, or appear to be a controlled substance if:

(a) Its finished dosage form has similar color, shape, and size of any controlled drug substance.

(b) Its finished dosage form has similar markings, on each dosage unit, as any controlled drug substance.

(c) Its finished dosage form container bears similar markings or printed material as any packaged control substance.

2. A person shall be deemed to have sold, furnished, transported, or to have arranged or offered to sell, furnish, or transport a substance which resembles, imitates, or appears to be a controlled substance if the person:

(a) Implied or expressed that the substance is a narcotic or non-narcotic controlled substance.

(b) Expressed or implied that the substance is of such a nature or appearance that the recipient will be able to sell, furnish, or give the substance as a controlled drug substance.

(c) By any other set of facts had reason to believe the substance would be used to imitate, resemble, or appear as a controlled drug substance. These may be:

1) Exchanged or demanded money or other valuable property as consideration for delivery of the substance and the amount of such consideration was substantially in excess of the reasonable value of the noncontrolled substance.

2) Size of purchase.

3) Location of purchase.

4) Time of purchase.

87-601 O - 82 - 13

APPENDIX J

[The following information is reproduced from the August 1981 Bulletin of the National Clearinghouse for Poison Control Centers (Vol. 25, No. 6)]

PHENYLPROPANOLAMINE WEIGHT CONTROL PRODUCTS

Overdoses of phenylpropanolamine (PPA) and other sympathomimetics have become an increasingly common problem handled by poison control centers and hospital emergency rooms. The major factor contributing to this has been the proliferation of OTC weight control products containing PPA. There are about 2 dozen PPA weight control products on the market. Solid dosage forms contain 25-50mg PPA (single release) or 37.5-75mg (sustained release), alone or combined with caffeine. Liquid forms contain 125mg PPA per ml. Increased marketing of OTC weight control products containing PPA began in 1979 following the recommendation of the FDA Advisory Review Panel on OTC Miscellaneous Internal Drug Products that PPA be classified as a Category I ingredient - safe and effective - for weight control, and the earlier removal of amphetamine for that purpose. Because FDA has not yet accepted the panel's recommendation, nor is it compelled to, what has been termed a "produce at your own risk situation" exists. The data on safety and efficacy of these products is being reexamined by FDA, and there is some internal pressure to classify PPA as a Category III ingredient which would require manufacturers to provide further evidence of safety and efficacy. Whatever the final decision, PPA weight control products will be on the market for several more years at least.

In addition to the OTC weight control products, another source of PPA being encountered more frequently are products variously referred to as amphetamine look-alikes, legal highs, rip-off street drugs, me-too generics, etc. These closely resemble amphetamine and other Rx stimulant drugs in appearance and may contain PPA, ephedrine and caffeine, alone or in various combinations. The identifying characteristics of these products are listed in the article following this one. Although several federal agencies are attempting to deal with the look-alike problem, the manufacture and sale of these products appears to be technically within the law.

Poison control case reports submitted to the Division of Poison Control document the sharp increase that has occurred in improper exposure and poisoning from PPA weight control products in the past few years. Figure 1 shows the trend from 1975 through 1980 in the frequency of poison control case report mentions of PPA products[1] by themselves (not combined with alcohol or other substances). Case report mentions of these products rose from 0.1% of all drug mentions in 1975 to 0.9% in 1980[2], and the fraction of all diet products, both Rx and OTC, for which they accounted rose from 11% to 68%. In persons aged 5 and older, PPA cases increased 10-fold from 0.1% of all drug cases in 1975 to 1.1% in 1980, doubling in frequency from 1979 to 1980. In children under 5, their frequency increased from 0.1% to 0.7%. Since these data do not include mentions of PPA combined with alcohol or other drug products, they underestimate the true frequency of PPA cases.

A similar increase occurred in the frequency of PPA related emergency room visits for persons older than 5 that were reported through the NIDA-DEA Drug Abuse Warning Network (DAWN)[3]. The frequency of "OTC diet aid" mentions in DAWN reports increased from 0.3% of all mentions in the last half of 1978 to 0.6% in the first half of 1980. Only sporadic reports of emergency room visits involving children under 5 were collected through the Consumer Product Safety Commission's National Electronic Injury Surveillance System.

Based on these data, it is estimated that on the order of 10,000 or more poison control cases and 1,000 emergency room visits involving PPA weight control products are now occurring each year.

Figure 1. Frequency of phenylpropanolamine cases

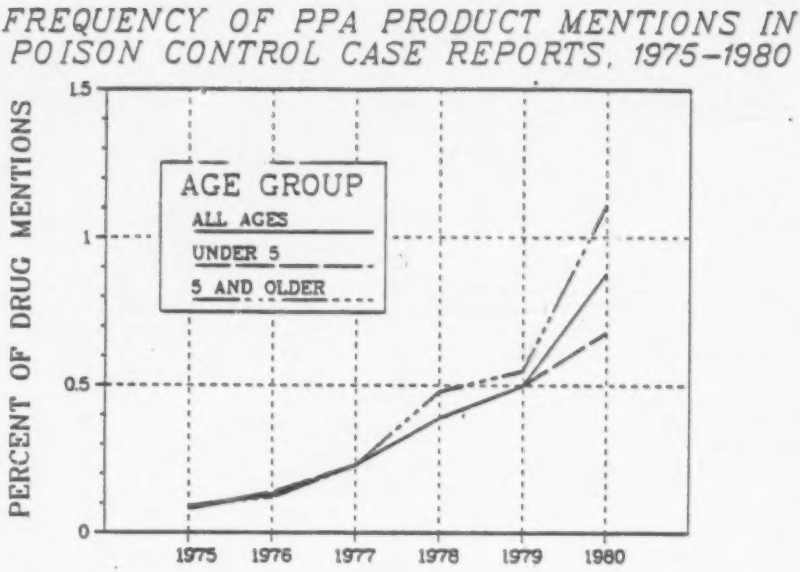
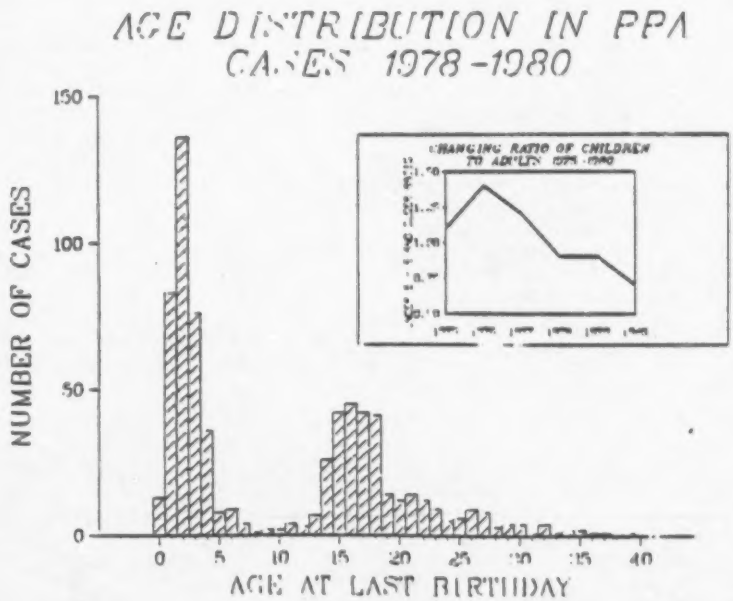


Figure 2. Age distribution of phenylpropanolamine cases



(PHENYLPROPANOLAMINE cont)

The age distribution of PPA exposure victims in poison control cases for 1978-1980 is shown in figure 2. The bimodal distribution with peaks at 1-3 years old and 14-18 is similar to that found with other OTC products that are ingested adventitiously by children and also used suicidally by young adults; the latter phenomenon being related more to the availability of OTC's than efficacy. Forty-two percent were children younger than 5, 49% were 5 and older, and 9% had no age reported. Forty-nine percent of those in the 5 and older group were 14 to 18 year olds, and 74% were female. Suicide gestures and attempts were involved in 49% of the cases in the 5 and older group, and substance abuse in 9%. Suicides in DAWN cases also accounted for 49% of the OTC diet aid mentions. The inset in figure 2 shows that the fraction of PPA cases involving children younger than 5 has been decreasing relative to adults. Ingestions in children may not be rising as fast as those in adults because many of the products employ unit dose packaging which, while it is technically not child resistant, does tend to limit children's access to drugs.

Signs and symptoms or hospital visits were reported in 13% of the 1978-1980 poison control cases for children and 58% of the cases for adults. No deaths were reported by poison control centers; however, reports of fatal cases have appeared in the literature and have been reported by Medical Examiners in the DAWN system. One death recently occurred in New Mexico in an otherwise healthy 20 year old female with a history of "amphetamine" use. High levels of PPA were found in the urine consistent with recent heavy use of an amphetamine look-alike containing PPA. Death was due to an intracerebral hemorrhage with no evidence of a preexisting vascular defect. Two other deaths in young males also occurred recently in New Mexico that were associated with amphetamine look-alikes containing ephedrine.

PPA produces a dose related increase in blood pressure. In a recent study, 12 of 37 healthy young subjects had peak supine diastolic pressures in excess of 100mm Hg 1.5-3 hrs after treatment with 85mg of PPA, some of them requiring antihypertensive treatment. The increase in blood pressure from lower doses was not as extreme. Symptoms reported by the study group included tingling feelings in the head, dizziness, palpitations, headache, tightness of the chest, tremor, nausea, lassitude and tinnitus. Overdoses and continuous use of PPA has been associated with severe hypertension, intracerebral hemorrhage, severe bifrontal headaches with nausea, postural hypotension, "psychotic reactions" and convulsions. Several cases of transient myocardial ischemia in young women associated with PPA have been reported to the FDA Divsion of Drug Experience. In most cases, the toxic effects of PPA resolve themselves in 6 to 48 hours following termination of the drug. Because of the risk of intracerebral hemorrhage, however, clinicians treating PPA overdoses may want to consider treatment with an antihypertensive agent such as phentolamine. (D.A.Brancato, B.I.Cohen, M.I.Fow)

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[1] Included are: Anorexin, Appedrine, Ayds Droplets, Biodrene Tablets, Dex-A-Diet, Dexatrim, Dietac (solid and drops), Diet Aid, Full Stop, Gobese, Hungrex, Obestat, Ordinex, Perma Thene 12, Prolamine, Propadrine, Slenderex, Slim-Eze, Slim One, Thinz Reducing Pills, Trim N Slim, Vita Slim, X-Drin, X-11 Tablets.

[2] Processing of 1980 data is only 40% complete.

[3] Drug Watch, July 1978-June 1980. National Institute on Drug Abuse, Division of Data and Information Development, Forcasting Branch. 5600 Fishers Lane, Rockville MD 20857.

AMPHETAMINE LOOK-ALIKES

The following is a listing of the physical description of drug products being promoted as "legal highs" which resemble amphetamine and other Rx stimulant drugs. All have been found to contain phenylpropanolamine, ephedrine and caffeine, alone or in combination.

Black capsules

Imprints	
127	8658
335	8858
18-789	18-585
DEX	18-985
RJS	

Yellow capsules

Imprints	
RJ8	RVJ

Miscellaneous Capsules

Color	Imprint	Contents
Blue/clear	127	Blue and white beads
White/clear	127	Green/oragnge/white beads
Black/clear	127	Orange/white beads
Green/clear	127	Green/white beads
Orange/clear	None	Red/white beads
Yellow/clear	None	Red/white beads
Pink/white	None	
Black/clear	17-875	Yellow/orange beads
Green/clear	None	Gray/white beads
Red/yellow tint/clear	None	Orange/green beads
Brown/yellow	None	

Tablets

Color	Imprint	Other
White	None	Double-scored
Peach	BT 72-200	
Green	165	Triangle-shaped
Pink	None	Heart-shaped single-scored

Source:
"Poison Information"
Vol. 5(3) April-May 1981
Nancy Newburn
University of California
School of Pharmacy

APPENDIX K

(68)

News Release

Center for Science in the Public Interest
1755 S Street, N.W. • Washington, D.C. 20009
(202) 332-9110

DIET PILLS BRANDED AS HAZARDOUS AND INEFFECTIVE

A non-profit citizens' group has urged tight restrictions on a popular weight-control drug whose use and misuse has been linked to high blood pressure, thousands of cases of poisoning, and even occasional psychotic incidents.

The Center for Science in the Public Interest (CSPI) has urged the Food and Drug Administration (FDA) to review recent damaging evidence concerning the drug and to ban its use in weight-control products. The drug, phenylpropanolamine (PPA), is an amphetamine-like chemical found in most non-prescription diet pills, including Appedrine, Control, Dexatrim, Dietac, Odrinex, and Prolamine.

In a related action, CSPI, four physicians, and Doctors Ought to Care, a non-profit doctors' organization, petitioned the Federal Trade Commission (FTC) to prohibit misleading advertisements for Dietac, one of the most widely marketed diet pills.

In documents filed with both the FDA and the FTC, CSPI presented the evidence showing that PPA is minimally effective as a diet aid and potentially dangerous. The risks arise from the drug's ability to stimulate the brain and to cause large increases in blood pressure. Recent clinical reports have indicated that in some cases normal doses of PPA may trigger psychotic behavior or life-threatening damage to blood vessels in the brain. Yet advertisements for Dietac include such reassuring claims as "contains no stimulant" and "clinically proven safe."

The group of petitioners called on the FTC to prohibit such deceptive claims, as well as other unsubstantiated statements that lead consumers to believe that PPA has been proven effective or approved by the government for weight control. Bruce Silverglade, CSPI's Legal Affairs Director, stated, "The Dietac media campaign represents a classic case of unfair and deceptive advertising. The manufacturer's failure to include a health warning in its advertisements violates established FTC rules." Dietac is produced by SmithKline Corporation.

CSPI's strongly-worded letter to the Commissioner of the FDA requested an accelerated review of PPA-containing diet pills, with a view toward removing these medications from the market. "The FDA has known for years about the shabby record of these products, but has never restricted their use, according to Bambi Batts Young, director of CSPI's Environment and Behavior Program. "Any further delay in banning them would senselessly jeopardize the health of a great number of consumers."

Young stressed that "Quick action by the FDA is urgent because of an alarming recent increase in the misuse of PPA for its stimulant effects." According to the FDA's Division of Poison Control, the nationwide network of poison control centers reported for 1980 approximately 10,000 cases treated for exposure to PPA from legitimate weight-control products. This figure represents a doubling of the cases seen in 1979.

The Center for Science in the Public Interest is a non-profit citizens' group that focuses on health issues. The group has recently been investigating hazardous substances that affect behavior and the nervous system.

Center for Science in the Public Interest
1755 S Street, N.W. • Washington, D.C. 20009
(202) 332-9110

October 19, 1981

Commissioner Arthur Hayes
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner Hayes:

We are writing to urge that the FDA move as quickly as possible to complete its review of weight-control products containing phenylpropanolamine (PPA). Since recent evidence indicates a significant hazard associated with this drug, and since the drug's effectiveness in promoting weight loss is highly questionable, any further delay in action would senselessly jeopardize the health of a great number of consumers.

Although the 1978 report of the FDA Advisory Review Panel on OTC Miscellaneous Internal Drug Products tentatively recommended that PPA-based diet aids should be considered safe and effective, many medical experts today disagree on both points. These physicians and scientists are disturbed about the continuing use of such medications because:

1. PPA is an amphetamine-like drug that has never been tested properly for its mental and behavioral effects, despite its established stimulant properties, and despite a number of clinical reports linking its use with moderate to severe behavioral problems;

2. studies conducted since 1978 have demonstrated that currently acceptable doses of PPA can trigger marked rises in blood pressure, even in healthy medical students, and it is known that overweight individuals have a greater-than-average incidence of hypertension, heart disease, and other disorders that could be dangerously aggravated by the drug's effects on the cardiovascular system;

3. all of the data now on public record, including information available through transcripts of the Advisory Review Panel's meetings, suggest that PPA is, at best, only marginally effective in contributing to weight loss, with little evidence that the losses can be maintained past a few months.

In addition, it has recently become clear that PPA products have enormous abuse potential. Capsules containing 50 mg of PPA (the same amount as is included in many diet pills), 25 mg of ephedrine (a related sympathomimetic), and caffeine (also found, combined with PPA, in many diet pills) are being packaged like amphetamines and sold widely on the streets and through national periodicals as "strongest stimulants you can buy without a prescription." Reports indicate

that these amphetamine "look-alikes" have become a popular fad that is appealing to teenagers and younger children, as well as to adults. Coinciding with this trend is a rapidly increasing misuse of the PPA-based diet aids themselves. According to the FDA Division of Poison Control, the nationwide network of poison control centers reported for 1980 approximately 10,000 cases treated for exposure to PPA from legitimate weight-control products. This figure represents a doubling of the cases seen in 1979.

Today, the Center for Science in the Public Interest (CSPI) submitted to the Federal Trade Commission a petition asking for a ban on misleading advertisements that promote PPA-based diet aids. CSPI was joined in this action by a group of medical experts who have a special interest and expertise in the use of these drugs. The petition (enclosed) details the scientific grounds for rejecting any claim that PPA has been proven either safe or effective for weight loss.

Under the circumstances, it is disturbing that the FDA's evaluation of PPA-based diet aids has been proceeding so slowly. It has been almost three years since the Advisory Review Panel issued its preliminary report on weight-control products. The data that the Panel used to support its recommendations have never been made available for scrutiny and comment by the general scientific community, and will remain inaccessible until the Panel's report is published as a "proposed monograph" in the Federal Register. As long as the publication of that Federal Register report is put off, manufacturers of PPA-based weight-control medications will be able to promote their questionable products with impunity.

We therefore request that you direct the Bureau of Drugs to expedite publication of the proposed monograph on weight-control products. We further request that the FDA consider the evidence that we have presented here when the agency prepares a preamble for that document. We submit that this evidence demonstrates that PPA-based diet aids are no more than marginally effective and that they do not meet the safety requirements of 21 CFR §330.10(a)(4)(i). As a result, we call upon the FDA to propose a ban on OTC distribution of these drugs.

Sincerely,

Bambi Batts Young

Bambi Batts Young, Ph.D.
Director, Environment and
Behavior Project

Michael F. Jacobson

Michael F. Jacobson, Ph.D.
Executive Director

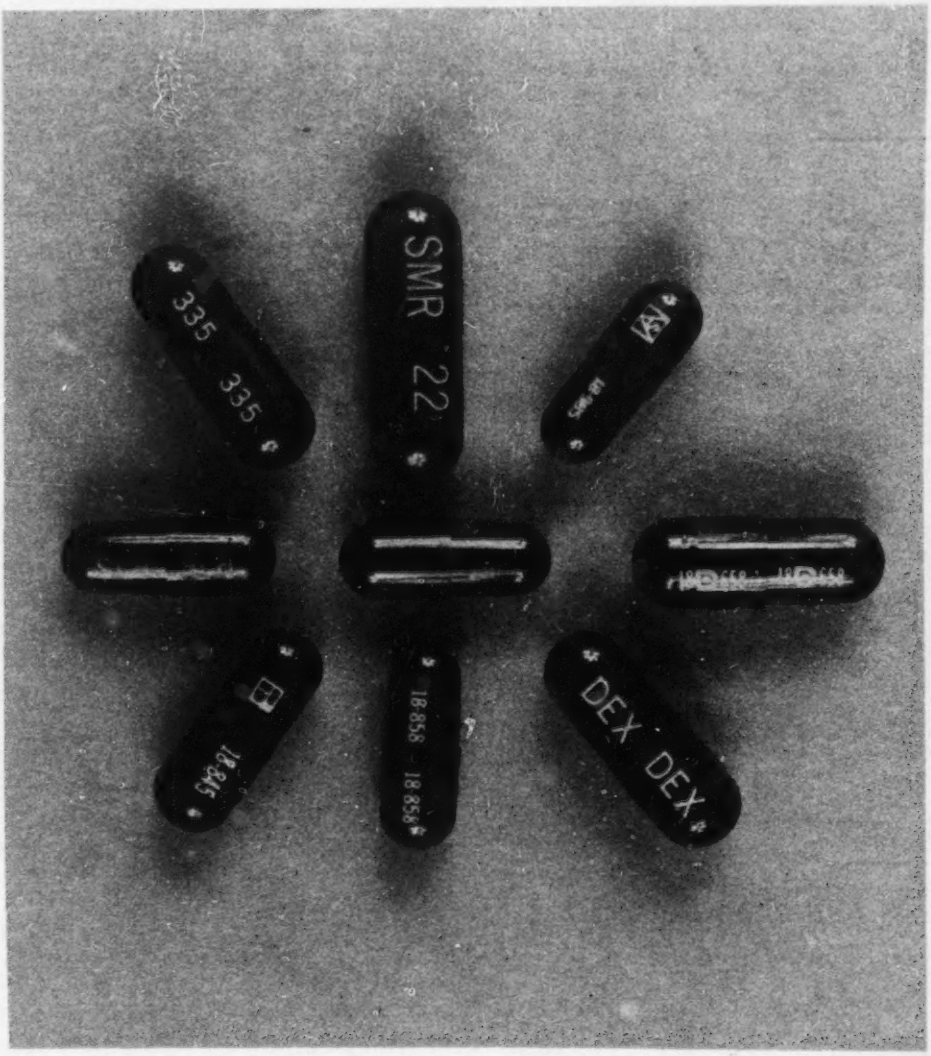
Bruce Silverglade

Bruce Silverglade
Director of Legal Affairs

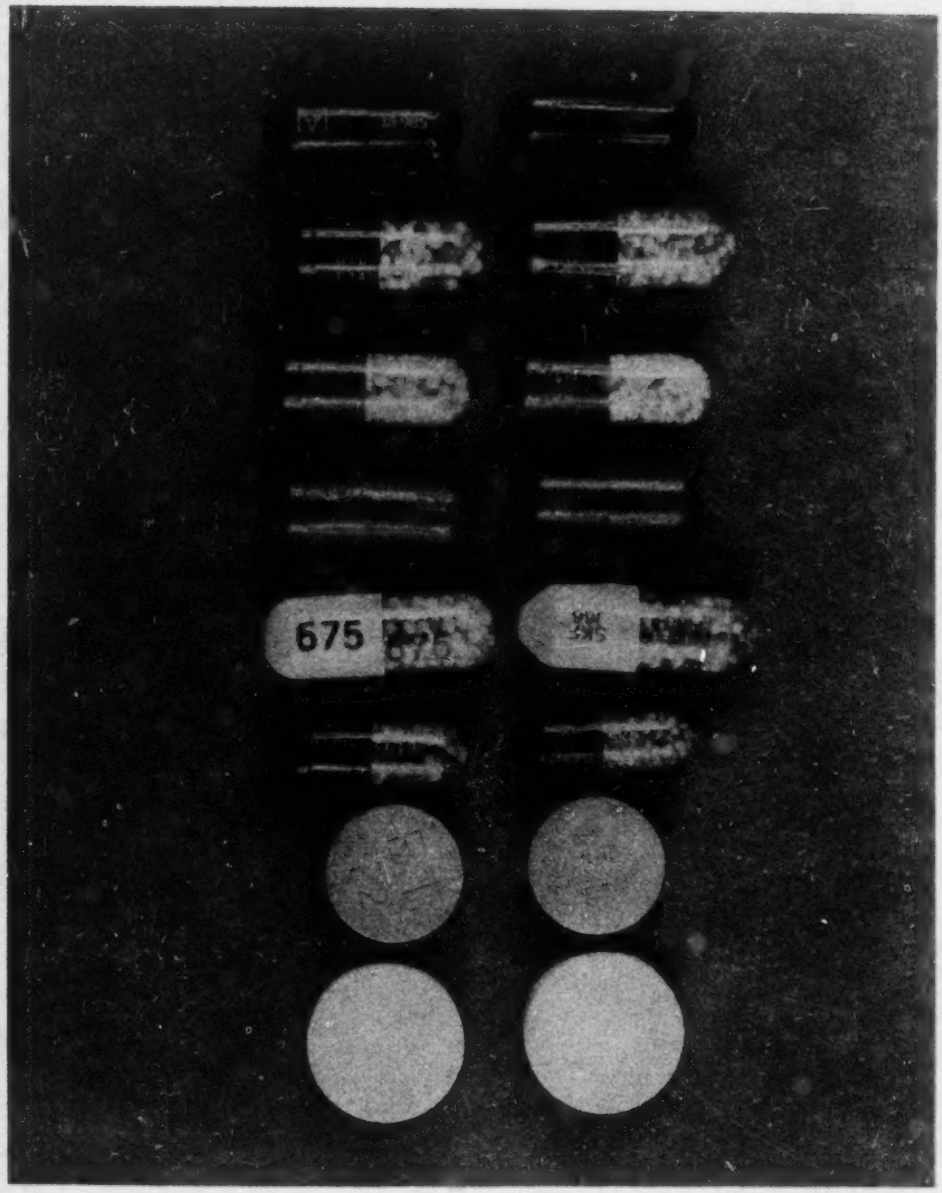
Encl.

APPENDIX L

Photographs of controlled substances and look-alike imitations.



Biphetamine capsule (center) surrounded by look-alike products.

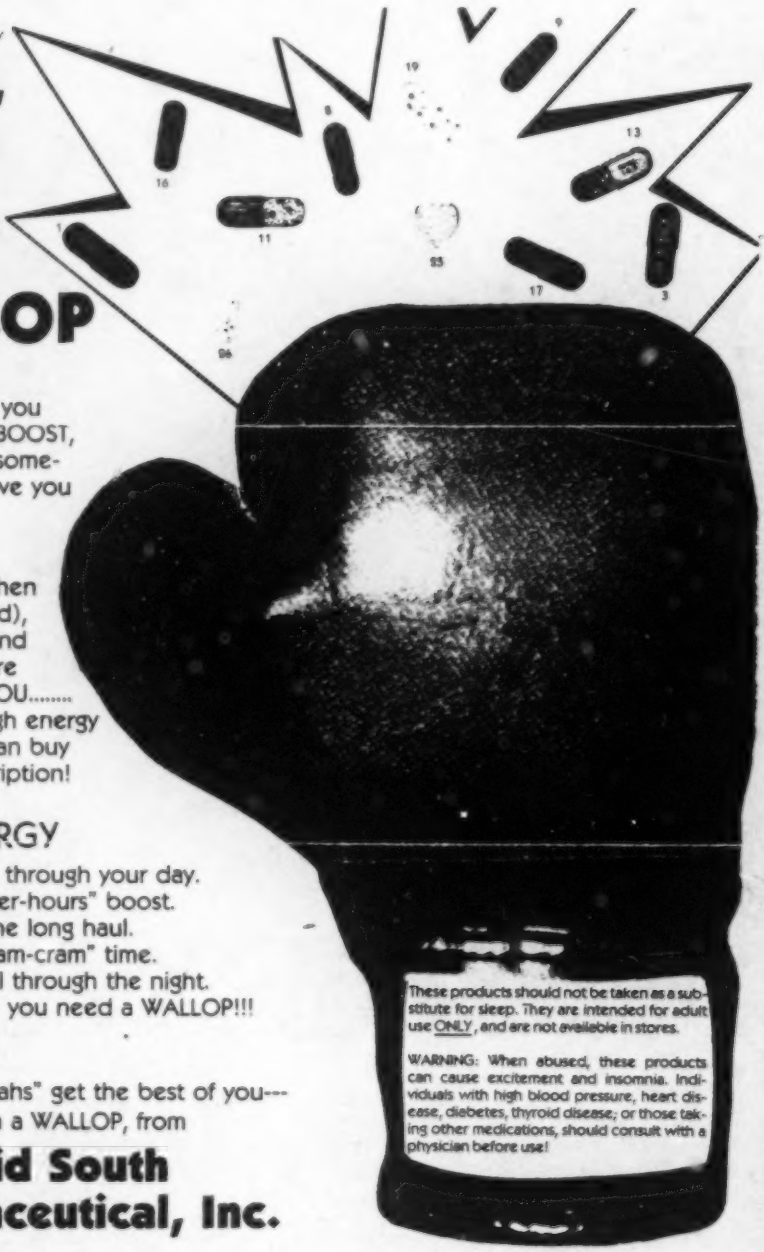


Capsules and tablets on the right are actual controlled substances; those on the left are look-alike products. Although the colors are not reproduced here, the original photograph (in the Committee's files) shows that the look-alike pills are indistinguishable in color from the products they imitate.

APPENDIX M

Examples of look-alike promotional materials.

WE'LL GIVE YOU THE WALLOP


These products should not be taken as a substitute for sleep. They are intended for adult use ONLY, and are not available in stores.
WARNING: When abused, these products can cause excitement and insomnia. Individuals with high blood pressure, heart disease, diabetes, thyroid disease, or those taking other medications, should consult with a physician before use!

If you ever feel you need an EXTRA BOOST, then we've got something that can give you the WALLOP!!!

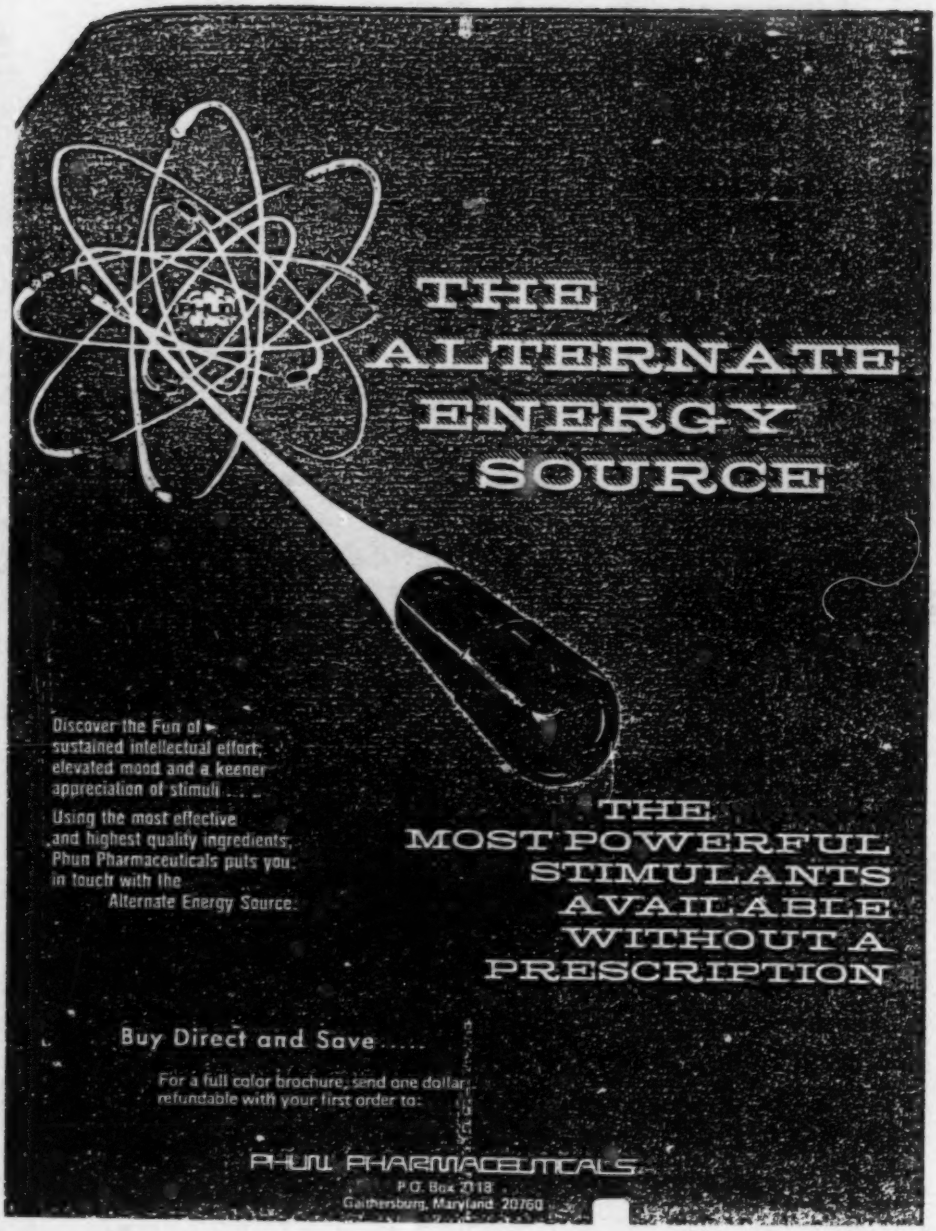
They're SAFE (when taken as directed), they're LEGAL, and best of all, they're AVAILABLE TO YOU..... the strongest high energy stimulants you can buy without a prescription!

EXTRA ENERGY

... To make it through your day.
... For an "after-hours" boost.
... To make the long haul.
... During "exam-cram" time.
... To work all through the night.
... Whenever you need a WALLOP!!!

Don't let the "blahs" get the best of you---
FIGHT BACK with a WALLOP, from

Mid South Pharmaceutical, Inc.


THE ALTERNATE ENERGY SOURCE
Discover the Fun of ► sustained intellectual effort, elevated mood and a keener appreciation of stimuli . . . .
Using the most effective and highest quality ingredients, Phun Pharmaceuticals puts you in touch with the Alternate Energy Source.
THE MOST POWERFUL STIMULANTS AVAILABLE WITHOUT A PRESCRIPTION
Buy Direct and Save . . . . .
For a full color brochure, send one dollar, refundable with your first order to:
PHUN PHARMACEUTICALS
P.O. Box 2118
Gaithersburg, Maryland 20760

EPHEDRINE SPEED

T.R. McWit Ephedrine Speed is real speed. One of the main ingredients in Ephedrine Speed is Ephedrine Sulfate. Ephedrine Sulfate is a legal stimulant that imitates Amphetamine. Ephedrine Sulfate is so similar to Amphetamine that another Ephedrine based drug called Desoxyephedrine HCl or Crystal Meth is classified as an Amphetamine under Schedule II of the Controlled Substance Act of 1970.

Amphetamine and Ephedrine Sulfate are both direct central nervous system stimulants. They both promote alertness and combat fatigue. They suppress the appetite effectively and relieve depression temporarily. All in all they give you energy which is what you need.

The current street value for a single hit of Ephedrine Speed, where they are consumed, is $1.00. The street value of a hit of Amphetamine is the same. A bottle (1000 hits) of Ephedrine Speed is $100.00 or 10¢ a hit. If large quantities are bought you can get as low as $25.00 a bottle or 2½¢ each. At a street value of $1,000.00 per bottle (when sold by single hits). Somebody is making quite a profit. Why not let it be you? We are not saying that you are going to net $900.00 to $975.00 per bottle. You should net profit $100.00 to $150.00 per bottle bringing the retail at your level of distribution to $250.00 to $125.00 depending on your market and quantity bought. Keep in mind that quantity is important to you and us. The more that is distributed the more is eaten. Sure you could sell them by the hit and make $900.00 to $975.00 net profit per bottle but it would take too long. In the same amount of time you could sell 20 bottles by the bottle and net $2,000.00 to $3,000.00. Let your customers do the hard work.

T.R. McWit Ephedrine Speed comes in 40 different capsules and tablets with different shapes and colors. Strengths vary too. Ephedrine Speed consists of a bitter confection of caffeine, Ephedrine Sulfate and Phenylpropanlamine HCl. We guarantee that our stimulants have more punch than caffeine.

Remember that you can sell them as speed. The law can not do anything as long as you don't sell them as Amphetamine or as any other controlled substance.

"VETERANS OF THE PILL BUSINESS"

T.R. McWit will meet any competitions price as long as you submit to us an ad or reciept of purchase that shows the stated price.

If you should need a certain stimulant that we don't carry in inventory, we will do our best to get it to you at regular T.R. McWit prices. Expect two weeks for final delivery of such merchandise.

Because of T.R. McWit buying power we may be able to sell you the same product that your present supplier offers you for a great deal less. Especially if his prices only make it feasible to buy in very large quantities when you only want a couple thousand of such product.

Contracts for large quantities over large or short periods of time are available to those persons who would like to get outragously low prices.

We are in business to serve you and the stimulants you need. Just give us a call if you have any questions or need a couple of tips. When calling use the regular number first. If no answer, then call the 24 hour service. Please leave your full name, address, telephone number and area code, plus exactly what you need. It will help if you will indicate the time you normally available at this number. If any probelm should arise in getting your order to you, we will contact you immediatly.

All orders will be shipped UPS Blue Lable C.O.D.. Cash only please. Expect 4 to 7 weekdays for delivery (4 weekdays if order is placed before noon).

Thank you for your time and cooperation. We hope this has been worth yours and our effort.

WELCOME TO T.R. McWIT

SAMPLES $5.00

QUANTITY	PRICE	TOTAL PRICE
100 - 900	$10.00 per 100	$10.00 - 90.00
1 bottle (1000)	$100.00	$100.00
5 bottles	$85.00	$425.00
10 bottles	$70.00	$700.00
25 bottles	$55.00	$1375.00
50 bottles	$40.00	$2000.00
100 or more bottles	$25.00	$2500.00 +

TELEPHONE: (305) 964-7102 24 HOUR SERVICE (305) 964-7209

ADDRESS: T. R. McWit
P. O. Box 6384
Lake Worth, Fla. 33461

Dear Friend:

You recently received a card and a short letter with a price list on our new products--Body Stimulants. Our response was fair. The greatest worries of the people who did respond were:

(1) IS IT COMPLETELY LEGAL: Yes, there is nothing in the tablets or capsules that's illegal or we could not sell them through the mail. We receive them from the factory through the mail also.

(2) ARE THEY SAFE: Yes, the only ingredients in all of them is caffiene and pseudephedrine. They give the speed-like effect. They contain 250 mg. caffiene and 25 mg. pseudephedrine. Caffiene is a stimulant found in coffee, tea and pop. Pseudephedrine is a mild stimulant used for relief of hay fever, asthma and nasal congestion, which adds to the speed-like effect. I have sold many thousands without one complaint, other than some are stronger than others. That's the way they are made to give a variety of effects. DEX, 335 and RJ8 are the strongest; the rest are medium to medium strong in effect.

(3) DO YOU HAVE ANY AFFILIATION WITH ANY LAW ENFORCEMENT AGENCY: No, I have no affiliation with any law enforcement agency.

(4) WILL MY ADDRESS BE GIVEN OUT TO OTHER BUSINESSES, ETC.: No, all records will be kept in strict confidence.

(5) WHY DON'T YOU JUST CALL THEM DIET PILLS: The Food and Drug Administration has strict criteria for diet pills, which these pills will not pass. But as stimulants, they have been tested by the F.D.A. and found safe and effective. So, to advertise them as diet pills could get us in trouble, but stimulants they are.

(6) WHY DON'T YOU ADVERTISE THEM NATIONALLY: No, we will not advertise to show or tell what they are, as many of our customers and their customers sell them as real speed. They are that good in the speed-like effect. If any of our customers try to advertise them, we will immediately stop sales to them. We sell like Avon, direct sales only.

(7) DO THEY SELL: Yes--we know they sell by the amount of repeat orders, especially repeat orders of larger quantities. We have had several people sell 20,000 or more on one weekend with no pills. Just by showing and passing out a few cards to friends, relatives and friends of friends and taking orders. This is no come-on--this is the truth. There is no reason why you can't do the same. Most of these people sold them as the real thing with no problems. But we cannot and will not suggest that you sell them as diet pills or speed. Once you purchase them, you sell them as you please, at a price you choose.

This is a fabulous money maker. The cards are a very effective tool to make more money. As you pass them out, tell people you can get anything on the card for X amount of dollars per thousand. Show them the best ones, and they will show their friends and word will get around. And you can start taking orders, and when you receive the stimulants, the money will start pouring in. In most cases, when you start you will want to sell hundreds. But if you keep on selling hundreds you will miss the great potential of these stimulants. We suggest you sell hundreds the first 4 to 6 weeks. After that, tell your customers you are only selling them by the thousand. It is also a good policy to give free samples to prospective customers of quantities, so they know what they are buying.

offer a price incentive to quantity customers. If you continue to sell hundreds as your main objective, then who will want to buy quantities for resale when they would be competing with you price-wise, and as far as losing hundreds, customers most will go on and order 1000, or you can tell them to split the cost with a friend or two. But the few customers you will lose by selling thousands only will be well worth it later on.

If you have any more questions, please feel free to call me, Tony Lamb, at 1-313-664-3964

After May 1, 1980, our new price list goes into effect. Also, we will not accept orders of less than 1000 Sorry--we can not mix orders of a single thousand. For orders of several thousand, you can mix your order by the thousand. For example--an order for 3000 can be 1000 DEX, 1000 RJ8, and 1000-335. Also, when ordering describe the capsule or tablet in full, plus any markings or numbers so we know for sure what you want. For example, dark green and clear capsules with #127 on it.

Please send registered check or money order to NORTHWESTERN ENTERPRISES, Box 280, Davison, Mich. 48423
non-registered checks must clear your bank before we can ship your order
This is the new price list which goes into effect on May 1, 1980.

1000 to 2000	$50 per thousand
3000 to 10,000	$40 per thousand
11,000 up	$35 per thousand

All orders shipped in plain package by United Parcel Service postage due.

Prices for 500,000 and 1,000,000 upon request.

I look forward to doing business with you in the near future. Also, for your convenience, you may phone your order in and wire the money Western Union. That way we can ship your order the next day.

TO HELP YOU GET STARTED WE ARE OFFERING AN INTRODUCTORY OFFER OF ONLY $40 per thousand. BUT YOU MUST ACT FAST AS THIS OFFER EXPIRES ON ~~5-10-~~ 1980 AND WE WILL NOT ACCEPT ORDERS FOR THIS SPECIAL INTRODUCTORY OFFER POST MARKED AFTER 5-10-80, SO ACT NOW AS THIS OFFER WILL NOT BE REPEATED. THANK YOU.

Apr 2 0 1980

Sincerely,

Tony M. Lamb

Tony Lamb

Extra cards $3.50 per hundred.